2024
PROGRAM ELEMENT EVALUATION REPORT

OF THE

RISK ASSESSMENT AND RISK MANAGEMENT ELEMENT

DEPARTMENT OF HEALTH
AND
ENVIRONMENTAL CONTROL
SOUTH CAROLINA

PREPARED BY

JANET E. TALBERT
SHELLFISH SPECIALIST
FDA OFFICE OF STATE COOPERATIVE PROGRAMS

ON

07/29/2024

PROGRAM ELEMENT EVALUATION REPORT

STATE: South Carolina (SC)

PROGRAM ELEMENT EVALUATED: Risk Assessment and Risk Management

FREQUENCY OF EVALUATION: Biennial

DATES OF EVALUATION: Infield Evaluation April 29th to May 3rd, 2024
Record Review June 4th to June 26th, 2024

PERIOD UNDER REVIEW: June 2022 – June 2024

A. Status of Previous Program Evaluation

a. Summary of Deficiencies from the 2022 PEER

No deficiencies noted in this evaluation.

b. State Actions to Correct Deficiencies from the 2022 PEER

There were none.

c. Status of Action Plans

No action plan was required.

d. FDA Follow-up Regarding Previous PEERs Deficiencies and Action Plans

The FDA was not required to follow-up on any deficiencies or action plans since the last evaluation.

B. Status of Follow-up Evaluation

No action plan evaluation was required.

C. Status of Current Evaluation

1. Current Findings

a. Administration [Chapter I. @.01 A.]

The SC Department of Health and Environmental Control (SCDHEC) is the Authority responsible for the administration of the SC shellfish sanitation program. The SCDHEC has established a statewide shellfish safety and sanitation program to regulate the required elements in Chapter I. @.01 A. (1). They are the primary agency responsible for meeting the requirements within the National Shellfish Sanitation Program Model Ordinance (NSSP MO). SC Department of Natural Resources (SCDNR) is responsible for shellfish resource management. The SCDHEC and the SCDNR responsibilities are outlined in an interagency memorandum of agreement (MOA) described in section C. 1.

d. *Shared Responsibilities*.

Specific to this evaluation, the SCDHEC is responsible for closure and reopening of growing areas due to shellfish-related illness outbreaks, conducting annual *Vibrio parahaemolyticus* (Vp) and *Vibrio vulnificus* (Vv) risk assessments, collecting environmental data to assess vibrio risk in harvesting areas, investigating shellfish related illnesses, participating in recalls, developing *Vibrio* control plans (VCPs), reporting annual shellfish landings data, and providing training to dealers and harvesters.

The SCDHEC meets the requirements of Chapter I. @.01 A.

b. State Laws and Regulations [Chapter I. @.01 B.]

SC meets the requirements of Chapter I. @.01 B. by having laws and regulations that provide an adequate legal basis for the safety and sanitary control of all program elements including but not limited to the elements outlined in Chapter I. @.01 A.

i. Statutes/Laws:

- The SC Code of Laws, 1976 Title 44 – Health, Chapter 1. Department of Health and Environmental Control.
  - Section 44-1-140(5) authorizes the SCDHEC to promulgate and enforce rules and regulations, specifically SC Regulation 61-47 Shellfish (SC R. 61-47), for public health for the classification of waters and for the safety and sanitation in the harvesting, storing, processing, handling and transportation of mollusks, fin fish and crustaceans.
  - Section 44-1-150 and Section 44-1-151 authorizes the SCDHEC to assign penalties for violating rules of the department and penalties for violations involving shellfish.
  - Title 44 sections involving shellfish can be found online: https://www.scstatehouse.gov/code/t44c001.php.

- The SC Code of Laws, 1976 Title 50 - Fish, Game and Watercraft, Chapter 5. Marine Resources Act.
  - Article 9 Shellfish, Section 50-5-997 provides the SCDNR the authority to issue permits and licenses to harvest shellfish during out of season months.
  - Article 25 Point System for Violations of Marine Resources Laws provides the SCDNR authority to suspend saltwater privileges for violations of the SCDHEC regulations promulgated pursuant to Section 44-1-140 related to the harvesting and handling of shellfish resulting in an adulterated product as defined in SC R. 61-47.
  - Title 50, Chapter 5. Articles 9 and 25 involving shellfish can be found online at https://www.scstatehouse.gov/code/t50c005.php.

ii. Regulation(s)

SC R. 61-47 Section C. HARVEST, HANDLING, AND TRANSPORTATION of Shellfish was reviewed to ensure compliance with NSSP MO Chapter I. @.01. B. SC R. 61-47 C.2.(b)(d-f) specifically addresses the vibrio risk assessment and risk management NSSP MO requirements and procedures. SC R. 61-47 C.2.(d) requires the SCDHEC to follow additional temperature controls designated in the latest version of the NSSP MO. The annually updated South Carolina *V*CP is written in accordance with the 2019 publication of the NSSP MO. See Attachment 1.

SC R. 61-47. H. 2. COMPLIANCE gives the SCDHEC the authority to:

- Deem shellfish are adulterated when not grown, harvested, stored, treated, transported, handled, shucked, packed, processed, sold, or offered for sale in compliance with this Regulation.
- Give order to stop sale, condemn, destroy, recall, or otherwise dispose of all shellfish or shellfish containers found to be adulterated.
- Notify enforcement officials for the United States Food and Drug Administration, as well as shellfish control authorities in states that are known to have received adulterated shellfish.
- Suspend or revoke permits or certificates.

SC R. 61-47. P. REMEDIES addresses additional enforcement of the regulation. This section authorizes the SCDHEC, at its discretion, to bring civil court proceedings to enforce provisions of SC R. 61-47 and to impose criminal sanctions for violations. Responsible parties can be held criminally liable for violations of any provision of SC R. 61-47 and shall be punishable in accordance with Section 44-1-150 and Section 44-1-151, Code of Laws of South Carolina, 1976, and any subsequent amendments.

c. Record Keeping [Chapter I. @.01 C.]

The SCDHEC meets the requirements of Chapter I. @.01 C. by maintaining records in central electronic files in Columbia, SC. Records are available upon request from the central file database and any of the three shellfish offices in Beaufort, Charleston, and Myrtle Beach, SC. The FDA obtained all records requested via email from the SCDHEC Myrtle Beach office.

d. Shared Responsibilities [Chapter I. @.01 D.]

The SCDHEC is the primary agency responsible for the administration and enforcement of the shellfish program. The SCDHEC shellfish program coordinates with the SCDHEC epidemiology department to carry out shellfish related illness investigations. According to their MOA, the SCDNR collects shellfish landings data required for the SCDHEC to send to the ISSC and to utilize in annual vibrio risk evaluations.

The SCDHEC meets the requirements of Chapter I. @.01 D.

e. Administrative Procedures [Chapter I. @.01 E.]

The SCDHEC has adequate administrative procedures to regulate shellfish harvesting, sale, shipment, facilities, shellfish processing procedures, product labeling, storage, handling, and packing, and shellfish dealer certifications and if deemed necessary, suspension of certifications.

The SCDHEC also has adequate administrative procedures and authority to establish, manage, and regulate shellfish growing area classifications and control of harvest per Chapter I. @.01 E. They have the procedures in place and authority to ensure that shellfish originate from approved and open growing areas and that shellfish shipped in interstate commerce originate from certified dealers located within the state; SC R.61-47 section G. Certification and Permitting Procedures. The SCDHEC does not have any MOAs with other states to allow dealers from SC to purchase shellstock harvested and landed in another state.

The SCDHEC has the authority and procedures to detain, condemn, seize, and embargo contaminated or adulterated shellfish products pursuant to SC R.61-47, sub-section H.2. Compliance. The SCDHEC has operating procedures in place to issue product recalls of shellfish deemed to be a health hazard to the public. The SCDHEC shellfish program staff are commissioned Class 1 Law Enforcement Officers with statewide jurisdiction and can enforce all state laws in South Carolina. The SCDHEC has procedures in place to issue fines and other penalties which helps to deter initial and repeat violations.

The SCDHEC complies with shellfish plant inspection standardization by having two (2) shellfish standardization officers (SSOs) and five (5) shellfish standardization inspectors (SSIs). The SCDHEC uses the NSSP MO Guidance Document: Shellfish Plant Inspection Standardization Procedures (ISSC/FDA, 2019) to standardize SSIs.

The SCDHEC meets the requirements of Chapter I. @.01 E.

f. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness. [Chapter I. @.01 F.]

The SCDHEC meets this requirement by having administrative procedures in place to investigate cases of epidemiologically implicated outbreaks of shellfish-related illnesses. In the event that the SCDHEC epidemiologists determine there is an epidemiologically implicated outbreak of shellfish-related Illness associated with shellfish that has been commercially harvested in SC, the SCDHEC will follow the shellfish investigative protocols in the “SCDHEC Shellfish Related Vibriosis Illness Investigation Protocol” (Attachment 2). This protocol is specific to vibriosis case investigations; however, the document notes that the Waterborne Disease Epidemiologist will follow the same protocol to notify the Environmental Affairs Office of Law Enforcement Shellfish Program in the event molluscan shellfish consumption is suspected as the source of illness related to a different type of infection (e.g., norovirus infection following oyster consumption). The SCDHEC standard operating procedures for shellfish related illness/illness outbreak response includes following all steps required in the 2019 NSSP MO. The requirement to follow the 2019 NSSP MO is included specifically in both the 2022 VCP and the 2022 Marine Biotoxin Contingency Plan.

The SCDHEC is the state agency responsible for conducting shellfish related illness investigations. SC Law §44-29-10 and Regulation §61-20 require reporting of conditions on the state's List of Reportable Conditions to the regional public health department. Reportable diseases include all *Vibrio* species and shellfish consumption related illnesses. The SCDHEC shellfish program officers, epidemiology staff, and food safety inspectors, all work within the SCDHEC to investigate, act on, and report all shellfish implicated cases to the designated authorities within the required timeframes.

g. Outbreaks of Shellfish-Related Illness [Chapter II. @.01]

Since there were no illness outbreaks, recalls, or growing area closures associated with SC shellfish during the period of this evaluation, the FDA was not able to evaluate conformance with the NSSP MO Chapter II. @.01 A.-G requirements.

The SCDHEC was involved in one recall involving oysters harvested and processed in the Republic of Korea. The recalled product was implicated in an outbreak of norovirus illness. The SCDHEC successfully traced all recalled product distributed to SC firms and ensured it was removed from the market.

Although no outbreaks of shellfish-related illness were associated with SC product and the FDA could not evaluate implementation of the Chapter II requirements, SC has procedures in place to meet the NSSP MO requirements as described below.

Chapter II. @.01 A.
In the event shellfish are implicated in an illness outbreak in SC, the SCDHEC Waterborne Disease Epidemiologist will determine if an epidemiological association exists between the illness and shellfish consumption.

Chapter II. @.01 B.
In cases where a link has been determined, the epidemiologist notifies the Shellfish Program Manager who then notifies the FDA Shellfish Specialist and conducts an investigation within 24 hours to determine if the illness is the result of post-harvest contamination, mishandling, or illegal harvesting and/or growing area related. The SCDHEC shellfish program officers will contact the certified shellfish shipper that sold the implicated shellfish and conduct a shellfish plant inspection and full records review including shellfish sale tags with harvest areas. When implicated shellfish are from a retail food establishment the shellfish program inspectors and the SCDHEC's Bureau of Environmental Services – Food Protection Program inspectors conduct a joint retail food inspection of the establishment including documentation of shellfish tags, invoices, and transportation records. All associated records are reviewed, and information is provided to the Waterborne Disease Epidemiologist.

Chapter II. @.01 C.
If the outbreak is not a result of post-harvest contamination or illegal harvest from a closed growing area and it is a single source from a SC open growing area, the SCDHEC shellfish program manager issues immediate closure of the harvest area, notifies the ISSC and the FDA shellfish specialist, initiates a recall if the SCDHEC deems appropriate, and sends a list of dealers shipping the implicated shellfish to the ISSC and the FDA. When a multi-source outbreak occurs, the SCDHEC places the implicated area(s) in a precautionary closure until it is determined per requirements in Chapter II. @.01 C. (2) to be from an SC harvest area.

Chapter II. @.01 D.
In cases where the SCDHEC investigation determines that illnesses are related to post-harvest contamination, mishandling, or illegal harvesting, the shellfish program manager will notify the ISSC and the FDA, initiate a recall if the SCDHEC deems appropriate, and send a list of dealers shipping the implicated shellfish to the ISSC and the FDA.

Chapter II. @.01 E.
If the SCDHEC cannot determine within 24 hours if the outbreak is from post-harvest contamination, mishandling, illegal harvest or is growing area related, the SCDHEC shellfish program manager will immediately place the harvest area in a precautionary closure and initiate recalls if the SCDHEC deems appropriate and effective. If it is determined the outbreak is not to related to the implicated growing area, the area will be reopened.

Chapter II. @.01 F.
If the implicated harvest area is closed due to naturally occurring pathogens and/or biotoxins, the SCDHEC will follow the requirements in Chapter II. @.01 F. as needed.

Chapter II. @.01 G.
In cases where the growing area is determined to be the problem, the SCDHEC will follow the procedures described in Chapter II. @.01 G. of the 2019 NSSP MO.

Chapter II. @.01 H.
Anytime the SCDHEC initiates a recall of shellfish products, they follow specific notification and recall procedures described in Chapter II. @.01 H. of the 2019 NSSP MO.

Chapter II. @.01 I.
Even though the SCDHEC has never had a situation to utilize NSSP MO Chapter II. @.01 I. their procedure to allow reconditioning of shellstock implicated in an outbreak is to review each on a case by case basis and follow the 2019 NSSP MO requirements. The SCDHEC does not allow reconditioning if the product is already at the retail level and out of the hands of the dealer. At this level the SCDHEC would deem the shellstock adulterated and require disposal. Additionally, if norovirus is suspected or confirmed, the product would be deemed adulterated and require disposal.

The SCDHEC meets the requirements of Chapter II. @.01 by having procedures in place.

h. Shellfish Related Illnesses Associated with Vibrio parahaemolyticus (V.p.) [Chapter II. @.02]

There were no closures to shellfish growing areas in 2022-2024 in SC due to *Vp* illnesses and there were no product recalls initiated by the SCDHEC in 2022-2024 due to *Vibrio* illnesses. The SCDHEC does not use the one vibrio illness per 100,000 servings criterion for regulatory action. Instead, closures would be based on the second option in the NSSP Model Ordinance at Chapter II. @.02 A. (1-3). SC did not exceed this criterion.

Three sporadic illnesses have been reported from oysters and one from clams during the last five years. A single case was linked to oysters harvested from SCS205 in March 2019. A single case was linked to oysters harvested from SCM704F in July 2022. A single case was linked to oysters harvested from SCM157 in April 2023, and a single case was linked to clams eaten raw from SCS117 in January 2019. There were nine other instances of single cases reported but, in all instances, multiple states and harvest areas were possible sources. No other illnesses have been epidemiologically linked to the consumption of commercially harvested South Carolina oysters or clams.

The SCDHEC meets the requirements of Chapter II. @.02.

i. Annual Assessment of Vibrio vulnificus and Vibrio parahaemolyticus Illnesses and Shellfish Production [Chapter II. @.03]

The SCDHEC annually assesses vibrio illnesses associated with the consumption of molluscan shellfish. The assessment reviewed for this evaluation includes a record of all vibrio shellfish associated illnesses reported within the state and from receiving states, the number of illnesses per event, and any actions taken in response to the illnesses.

The SCDHEC determined in the 2024 *Vv* Risk Evaluation and 2024 *Vp* Risk Evaluation that SC is in a low risk category for both *Vv* and *Vp* illnesses, and extremely low risk for *Vv* and *Vp* outbreaks.

No *Vv* illnesses have been epidemiologically linked to the consumption of commercially harvested South Carolina oysters during this five-year review period. Single cases of *Vv* were reported implicating oysters consumed on October 4, 2019, and clams on October 7, 2019. Traceback indicated seven (7) different growing areas over three states as possible sources. *Vp* illness information is listed in section C. 1. h. *Shellfish Related Illnesses Associated with Vibrio parahaemolyticus* and Attachment 1.

The SCDHEC meets the requirements of Chapter II. @.03 A.

Pursuant to Chapter II. @.03 B., the SCDHEC has reported annual shellfish landings data for the type and volume of shellfish harvested in SC to the ISSC. The SCDNR collects monthly shellfish harvest logs and supplies the landings data annually to the SCDHEC for distribution.

The SCDHEC meets the requirements of Chapter II. @.03 B.

j. Presence of Human Pathogens in Shellfish Meats [Chapter II. @.04]

SC has not determined that human pathogens are present in shellfish meats and therefore has not had to implement Chapter II. @.04.

k. Presence of Toxic Substances in Shellfish Meats [Chapter II. @.05]

SC has not determined the presence of toxic substances in shellfish meats and therefore has not had to implement the requirements of Chapter II. @.05.

l. Vibrio vulnificus Control Plan [Chapter II. @.06]

Wild stock oyster and hard clam harvesting in South Carolina is closed during warmer months from May 15th through September 30th. 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 as well as to preserve the harvest of hard clams.

The SCDHEC has implemented additional harvest restrictions from approximately May 28th thru September 30th based on increased water and air temperatures. Time to temperature controls are in effect during the vibrio control months for the harvest of maricultured oysters. Oysters are continuously submerged for 14 days prior to harvest and delivered to a certified shipper before 10:00 AM on the same day of harvest. If oysters are to be delivered after 10:00 AM the same day of harvest, they are immediately iced upon removal from the water and delivered to a certified shipper no more than four hours from the start of harvest. The certified dealer has a maximum of two hours to reduce the internal temperature of the oysters to 50º F or less. Summer aquaculture harvest plans must be demonstrated to the SCDHEC and approved annually prior to summer harvest permitting. See Attachment 1.

The SCDHEC meets the requirements of Chapter II. @.06.

m. Vibrio parahaemolyticus Control Plan [Chapter II. @.07]

The SCDHEC has a written VCP that covers both *Vv* and *Vp* risks. Because the controls described above are sufficient to control both *Vv* and *Vp*, a separate *Vp* control plan for oysters is not required by the NSSP MO. No changes have occurred in the *Vp* risk to warrant any change to the current VCP. The South Carolina time-temperature controls meet the requirements of the NSSP MO. See Attachment 1 for details.

The SCDHEC meets the requirements of Chapter II. @.07.

n. Laboratory Element [Chapter III. @.01 and @.02]

There are two labs supporting the South Carolina Shellfish Program.

- Environmental Affairs Lowcountry Charleston Laboratory in Charleston, South Carolina is currently conforming to NSSP requirements, however this laboratory does not currently perform any methods related to opening after an illness (Biotoxin or *Vibrio* related).

- Environmental Affairs Lowcountry Beaufort Laboratory in Beaufort, South Carolina is currently conforming to NSSP requirements, however this laboratory does not currently perform any methods related to opening after an illness (Biotoxin or *Vibrio* related).

The SCDHEC is in conformance with the requirements of Chapter III. @.01 and @.02.

o. In-field Compliance Evaluation

An in-field evaluation was conducted for this RARM PEER. The FDA accompanied the SCDHEC officers and the harvester/dealer during a visit to the dealer's shellstock shipping facility and aquaculture farm May 1-2, 2024, to observe the certified dealer's

Summer Harvest Operations Plan procedures for the SCDHEC to approve their Out of Season Harvest Permit. Prior to summer harvest during vibrio control months, certified shellfish dealers must submit written summer harvest operations plans, summer HACCP plans, and conduct an in-field exercise each year to ensure they meet compliance with time to temperature requirements in the SC VCP and the 2019 NSSP MO.

i. During the visit to the certified dealer facility and dock, the dealer conducted a walkthrough of their summer harvest operations plan where the next steps specified in the dealer's summer operations plan were implemented. This began at the dock where the dealer showed how harvest boats offload oysters under various tidal conditions, then walked through oyster receiving, transfer steps, and placement of oysters into firm's refrigerated cooler (verified $\leq 45^{o}$ F) where shellstock meat temperature is monitored with a calibrated thermometer and recorded. Cool down to $\leq 50^{o}$ F is required within two (2) hours of receipt and prior to shipping. The FDA verified actual oyster temperatures and firm's cooler temperature were meeting requirements. Clams were not present at this facility.

ii. The FDA reviewed vibrio controls, HACCP plans, harvest, receiving, labeling, and time to temperature requirement records for the past two years for verification and compliance with the NSSP MO. No compliance issues were identified.

iii. SC does not have PHP plants.

iv. The FDA accompanied the SCDHEC officers to the aquaculture farm sites to observe operations and verify bird mitigation actions were not required. No birds and no accumulation of bird feces was observed by the FDA on the gear at any of the aquaculture farms visited for this exercise. The dealer did show the FDA one of their bird mitigation control kites they had on hand in case bird mitigation is needed.

The SCDHEC meets the requirements of the in-field compliance evaluation.

2. Corrective Actions Taken by State

None were required.

3. Action Plan(s)

None were required.

4. State Program Accomplishments

During the period covered by this evaluation, the SCDHEC Shellfish Program has successfully conducted effective shellfish recalls by coordinating and communicating with state and local agencies, shellfish dealers, retail businesses, and the FDA. Their actions ensured public safety by prompt tracking of suspected shellfish product and removal from commerce.

The SCDHEC Shellfish Officers successfully validated and trained all summer harvest dealers and harvesters prior to implementing summer harvest vibrio control plans and

have maintained all Management By Objective (MBO's) commitments of all growing areas despite having two vacancies in the Beaufort Regional Office. This was accomplished by reallocating staff from the northern regions to assist with all MBO efforts within the Shellfish Program.

5. New or Emerging Concerns

   The FDA did not identify any new or emerging concerns during the evaluation.

6. Technical Assistance and Training Requested by the State

   During this review period the SCDHEC and the SC Sea Grant Consortium requested a special oyster re-submergence study from the Vibrio Technical Assistance and Research Board (VARB). With the assistance of the FDA Dauphin Island Research Laboratory, The SCDHEC was approved for the special study by the VARB and has officially started the study in July 2024. The study will be concluded in the summer of 2025. Ms. Janet Talbert and the FDA have provided technical assistance training to the SCDHEC staff throughout this review period as well and the SCDHEC is very appreciative of the technical assistance the FDA provides, (M. Marshall, email communication, July 23, 2024).

7. Summary of the State's Response to FDA Evaluation

   The SCDHEC concurs with the FDA's evaluation of this Risk Assessment and Risk Management program element evaluation. We would like to give a huge thanks for all the hard work and assistance Ms. Janet Talbert provides our state each day. Ms. Talbert is always available whenever technical assistance is needed. With continued support and assistance from the FDA, the SCDHEC Shellfish Program will continue to be successful with implementing NSSP MO requirements, (M. Marshall, email communication, July 23, 2024).

8. Conclusion

   The state of South Carolina's Risk Assessment and Risk Management program element is in overall compliance with the NSSP MO. The FDA's 2022-2024 PEER did not identify any program deficiencies, new or emerging concerns, and did not make any recommendations. The next program element evaluation will be conducted in 2026.

9. FDA Recommendations

   The FDA has no recommendations because of this evaluation.

10. Acknowledgements

    The FDA would like to thank Mike Marshall for planning the infield portion of the evaluation and providing information and expertise addressing all aspects of the RARM evaluation. The FDA would especially like to thank Ryan Reed for planning and participating in the Charleston and a portion of the Low Country growing areas infield evaluation and Josh Reid for planning and participating in the Low Country growing areas evaluation as well as making arrangements for the infield SC Summer Harvest Operations Plan and permitting approval exercise.

11. Attachment(s)

Attachment 1. SC 2024 *Vibrio* Risk Assessments and *Vibrio* Control Plan - 14 pages.
Attachment 2. The SCDHEC Shellfish Related Vibriosis Illness Investigation Protocol – 1 page.
Attachment 3. SC 2024 Marine Biotoxin Contingency Plan - 6 pages.

South Carolina Vibrio Control Plan

April 2024

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 can be unreliable. SCDHEC water temperature data are recorded to the nearest degree Centigrade utilizing calibrated thermometers during each shellfish water quality-sampling event. This data has been averaged by month for the period January

2019 - December 2023. Data was analyzed and is summarized for the month of September below in Table 4.

(4) Air temperature data are available from the National Weather Service and from SCDHEC shellfish water quality-sampling events. Internal data was used for 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) The wild stock harvesting of oysters and hard clams 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 harvesting are accomplished using hand labor and tools. Most 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 are required to be continuously submerged for 14 days within 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 Shipper no more than four hours from the start of harvest. Upon receipt the Certified Shipper has a maximum of two hours to reduce the internal temperature of the oysters to 50 degrees F or less.

(7) Most oysters produced in South Carolina are used for oyster "roasts", although limited quantities of single oysters are 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 2024, 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, 2024. 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 two or more illnesses from a growing area occur.

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 from oysters and one from clams during last five years. A single case linked to oysters harvested from SCS205 in March 2019. A single case linked to oysters harvested from SCM704F in July 2022. A single case linked to oysters harvested from SCM157 in April 2023. 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 in May 2023 were traced back to 11 growing areas in several states which were NC-E6, PE 2, PEI 3B, Lease #182 – Yeocomica River VA, MA-CCB-13, MA-BB4, PEI 5T, VA Hog Island Bay, SCM704F, MD QA534, and PE 2G. A single case from the consumption of raw oysters in September 2023 were traced back to 7 growing areas in several states which were

SCM703F, Damariscotta River Area Q, VA Milford Haven, CCB-11-MA, PE 2G, CCB-31-MA, and VA Hog Island. 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 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 in April 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.

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 can be unreliable. SCDHEC water temperature data are recorded to the nearest degree Centigrade utilizing calibrated thermometers during each shellfish water quality- sampling event. This data has been averaged by month for the period January 2019 – December 2023. Data was analyzed and is summarized for the month of September below in Table 4.

(4) Air temperature data are available from the National Weather Service and SCDHEC shellfish water-quality sampling events. Internal data was used for 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) The wild stock oyster and hard clam 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 harvesting are accomplished using hand labor and tools. Most 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 are required to be continuously submerged for 14 days within 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 Shipper no more than four hours from the start of harvest. Upon receipt the Certified Shipper has a maximum of two hours to reduce the internal temperature of the oysters to 50 degrees F or less.

(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 2024, 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 restrictions will be implemented from May 28 thru September 30, 2024. 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 two or more illnesses from a growing area occur.

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 2019-2023

Month	Degrees Fahrenheit
January	54
February	54
March	60
April	67
May	75
June	81
July	85
August	84
September	81
October	74
November	64
December	57

Table 2

South Carolina Shellfish Growing Area 5 Year Monthly Average Air Temperatures 2019-2023

Month	Degrees Fahrenheit
January	54
February	59
March	61
April	69
May	77
June	81
July	85
August	84
September	80
October	74
November	62
December	55

Table 3

South Carolina Shellfish Growing Area 5 Year Monthly Average Salinity 2019-2023

Month	PPT
January	24
February	24
March	22
April	23
May	26
June	25
July	27
August	26
September	27
October	28
November	28
December	28

Healthy People. Healthy Communities.

SCDHEC Shellfish Related Vibriosis Illness Investigation Protocol

1. A Vibriosis Case is entered into the Electronic Disease Surveillance System (I.e., SCION) after receipt of a laboratory report or notification from a healthcare reporting partner indicating a patient infection with *Vibrio* species.
2. Regional Epidemiology staff investigate all vibriosis cases in SCION and attempt to interview case-patients using a standardized questionnaire format to collect pertinent information.
3. Upon interview, if the case-patient reports molluscan shellfish consumption prior to illness onset, the Waterborne Disease Epidemiologist in the Division of Acute Disease Epidemiology is notified by Regional Epidemiology staff.
4. The Waterborne Disease Epidemiologist reviews relevant information related to the case-patient's shellfish exposure and notifies the Environmental Affairs (EA) – Office of Law Enforcement (OLE) – Shellfish Program with this information.
5. The EA OLE – Shellfish Program will contact the certified shellfish shipper that sold the implicated shellfish and conduct a shellfish plant inspection and full records review and provide information including shellfish Sale Tags with Harvest Areas to the Waterborne Disease Epidemiologist.
6. When implicated shellfish are from a retail food establishment the EA OLE – Shellfish Program will first contact SCDHEC's Bureau of Environmental Services – Food Protection Program and conduct a joint retail food inspection of the establishment. All associated records are reviewed and information including shellfish Sale Tags with Harvest Areas are provided to the Waterborne Disease Epidemiologist.
7. The Waterborne Disease Epidemiologist completes the Cholera and Other Vibrio Illness Surveillance (COVIS) report form and submits this form including the shellfish Sale Tags information to the U.S. Centers for Disease Control and Prevention (CDC).

Note: This protocol is specific to vibriosis case investigations, however, the Waterborne Disease Epidemiologist will follow the same protocol to notify the EA OLE – Shellfish Program in the event molluscan shellfish consumption is suspected as the source of illness related to a different type of infection (e.g., norovirus infection following oyster consumption).

Rachel Radcliffe, DVM, MPH
Division of Acute Disease Epidemiology

Mike A. Marshall
EA OLE – Shellfish Program

Attachment 3. SCDHEC 2024 Marine Biotoxin Contingency Plan

South Carolina Department of Health and Environmental Control

Environmental Affairs – Office of Law Enforcement
Shellfish Sanitation Program

MARINE BIOTOXIN CONTINGENCY PLAN

March 2024

INTRODUCTION

Phytoplankton are tiny plant-like cells that are a natural part of the aquatic environment and provide a food source for many marine organisms, including filter-feeding shellfish. However, at times these cells can proliferate and form toxic harmful algal blooms (HABs.) Impacts from HABs are diverse, with the most significant associated with the accumulation of algal toxins in shellfish which can be harmful to humans if consumed or ingested. The resulting human poisoning syndromes linked to the consumption of shellfish have been given the names paralytic (PSP), amnesic (ASP), neurotoxic (NSP), diarrhetic (DSP), and Azaspiracid (AZP) shellfish poisoning to describe primary symptoms, or the toxins involved. Except for ASP, all are caused by biotoxins synthesized by dinoflagellates; the ASP toxin, domoic acid, is produced predominantly by diatoms within the genus *Pseudo-nitzschia*.

South Carolina has not historically experienced any incidents with HAB events or biotoxins impacting shellfish growing areas. One rare instance of Karenia brevis "Red Tide" occurred in the late 1980's that affected the coast of North Carolina and northern portions of South Carolina due to a bloom off Florida's west coast that was then transported to the east coast by the Florida Current – Gulf Stream. Although HAB events in South Carolina are rare the possibility of a future event is conceivable. Therefore, to meet the National Shellfish Sanitation Program (NSSP) requirements, the South Carolina Department of Health & Environmental Control has developed and adopted a **Marine Biotoxin Contingency Plan** for all marine and estuarine shellfish growing areas addressing the marine biotoxins mentioned above.

National Shellfish Sanitation Program Model Ordinance Requirements
Section II Model Ordinance – Chapter IV. Shellstock Growing Areas
Marine Biotoxin Control

The South Carolina Department of Health and Environmental Control's Marine Biotoxin Contingency Plan defines the administrative procedures and resources necessary to accomplish the following requirements from the 2019 National Shellfish Sanitation Program Model Ordinance.

A. Contingency Plan

(5) The Authority shall develop and adopt a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas addressing the management of PSP, ASP, NSP, diarrhetic shellfish poisoning (DSP) and Azaspiracid shellfish poisoning (AZP) in the event of the emergence of a toxin-producing phytoplankton that has not historically occurred, or an illness outbreak caused by marine biotoxins.

(6) The plan shall define the administrative procedures and resources necessary to accomplish the following:

- Initiate an emergency shellfish sampling program;
- Close growing areas and embargo shellfish;
- Prevent harvesting of contaminated species;
- Provide for product recall;
- Disseminate information on the occurrences of toxic algal blooms and/or toxicity in shellfish meats to adjacent States and federal partners, shellfish industry, and local health agencies;
- Coordinate control actions taken by Authorities and Federal agencies; and
- Establish reopening criteria including the number of samples over what period of time.

Marine Biotoxin Contingency Plan Resources & Administrative Procedures

Initiate an Emergency Shellfish Sampling Program

The South Carolina Department of Health and Environmental Control (SCDHEC), Environmental Affairs – Office of Law Enforcement – Shellfish Sanitation Program has field offices located in Horry, Charleston, and Beaufort counties which encompasses the entire South Carolina coastline where shellfish can grow. Phytoplankton monitoring occurs on a continuous basis in South Carolina. Officers within the Shellfish

Sanitation Program sample all shellfish growing waters on a routine basis and would assist as an early warning system if a harmful algal bloom (HAB) event were to occur. SCDHEC's Bureau of Water, Aquatic Science Program has dedicated and trained staff that conducts sampling year round for HABs. The Aquatic Science Program also utilizes real-time sampling data on the agency's GIS Harmful Algal Bloom App which shows mapping for statewide monitoring stations and provides information on advisories and watches.

SCDHEC recognizes, and will rely upon, the National Oceanic and Atmospheric Administration's (NOAA), National Centers for Coastal Ocean Science's (NCCOS) division and laboratory located in Charleston, South Carolina for assistance with any HAB events that may occur. NOAA's NCCOS Hollings Marine Laboratory which performs HAB forecasting, and sample analysis provides an excellent early warning system for health officials and environmental managers for shellfish bed closures. SCDHEC receives NOAA's NCCOS, the Florida Department of Fish & Wildlife Conservation Commission (FWC), and Florida's Department of Environmental Protection's (FLDEP) weekly HAB forecasting and monitoring reports via email. SCDHEC is in regular contact with the North Carolina Division of Marine Fisheries, the Georgia Department of Natural Resources, and FWC and would be notified by phone and email of any HAB events that may occur adjacent to South Carolina growing waters. Upon notification, SCDHEC will maintain the necessary communications with these agencies to evaluate all relevant data. If a HAB's species and action/threat level were identified by SCDHEC then staff would be alerted immediately by phone and email of the species and location. SCDHEC has an Emergency Response Team (ERT) that responds to HAB events and other environmental emergency events such as spills, fish kills, and sanitary sewer overflows 24 hours a day seven days per week. HABs events can be reported by email or phone by calling 1-888-481-0125 by the public, agency staff, and/or other municipal, county, or state agencies.

Should a HAB emergency event be tracked to South Carolina or begin in growing waters, the SCDHEC Shellfish Sanitation Program Manager located in the Pee Dee Myrtle Beach Field Office will initiate the HAB response. Assignments for sampling shellfish growing areas will be relayed to each appropriate field office. The northern coast of South Carolina will be sampled by the Pee Dee Myrtle Beach Office Staff, the central portions of the coastline will be sampled by the Lowcountry Charleston Office Staff, and the southern portions of the coastline will be sampled by the Lowcountry Beaufort Office Staff. Each office will be provided sampling equipment and storage capabilities for samples and all sample analysis will be performed by a certified laboratory. SCDHEC staff will coordinate the collection and

analysis of all samples and utilize sampling results, field reports, and hydrographic and meteorological data to determine the severity and extent of the harmful algal bloom.

Close Growing Areas and Embargo Shellfish

All shellfish growing areas will be closed under statutory authority given to SCDHEC if it is determined that shellfish growing waters will or may be impacted by a HAB event. SCDHEC Shellfish Regulation 61- 47, Section B.(2) states that, "The Department may also designate a growing area as a closed area and prohibit harvesting when it determines that conditions have occurred that may potentially render shellfish unsafe for human consumption."

Additionally, SCDHEC Regulation 61-47, Section H.2.(d)(1) and (2) gives the SCDHEC Shellfish Program the authority to temporarily or permanently issue an order to stop sale, condemn, destroy, recall, or otherwise dispose of all shellfish or shellfish containers found to be adulterated. Any shellfish embargoed or recalled will follow all current NSSP requirements and SCDHEC regulations. Upon the identification of a HAB event a closure can occur immediately. All emergency shellfish growing area closures are administered and executed by the SCDHEC Shellfish Program Manager in coordination with regional SCDHEC Shellfish Officers.

Prevent Harvesting of Contaminated Species

All SCDHEC, Environmental Affairs – Office of Law Enforcement, Shellfish Program staff are commissioned Class 1 Law Enforcement Officers with statewide jurisdiction and can enforce all state laws in South Carolina. SCDHEC Shellfish Regulation 61-47, Section P.(2) Criminal Liability, specifically states that, " any violation of any provision of this Regulation shall be punishable in accordance with Section 44-1-150 and 44-1-151, Code of Laws of South Carolina, 1976, and any subsequent amendments." These statutes give all SCDHEC Shellfish Officers the authority to prohibit the taking, processing, or sale of any molluscan shellfish that is or potentially been deemed unsafe for human consumption. All closed shellfish growing area waters will be patrolled by SCDHEC Officers not only during the day but during nights, weekends, and holidays if the closure is in place. All patrol activities will be identical to closed area patrols of other growing areas and Officers will patrol areas by land, water, and air. SCDHEC Officers utilize specialized equipment such as drones, boats, night vision, and thermal monoculars to prevent the illegal harvesting of shellfish from closed growing waters.

Provide for Product Recall

In the event of a product recall, SCDHEC would be the administrative authority under SCDHEC Shellfish Regulation 61-47, Section H.2.(d)(1) and (2) to ensure that the statutory requirements were followed and adhered to. All product recalls would be initiated within 24 hours by the SCDHEC Shellfish Program Manager.

Disseminate Information on the occurrences of Toxic Algal Blooms and/or Toxicity in Shellfish Meats to adjacent States and Federal Partners, Shellfish Industry, and Local Health Agencies

SCDHEC is the responsible agency to disseminate all information to the public, other states, the shellfish industry, and federal partners. The notification of a HAB event will occur as follows:

(1) **Public:** The SCDHEC Shellfish Program Manager will immediately contact the SCDHEC Media Relations Office and prepare a press release that will be published on the SCDHEC website, social media, and to all media outlets in the affected growing areas. The Shellfish Program Manager will update the SCDHEC GIS Emergency Closure Map which is located at https://scdhec.gov/food-safety/shellfish-monitoring-program-overview/shellfish-closure- updates. The Shellfish Program Manager will also update the SCDHEC Closure Hotline at 1-800- 285-1618 with all pertinent growing area information. The Shellfish Program Manager will directly notify SCDHEC's Division of Food Protection to ensure retail markets, restaurants, and mobile food truck operations are directly notified. The Shellfish Program Manager will also contact the SCDHEC Public Health – Bureau of Communicable Disease Prevention and Control State Epidemiologist to ensure all SCDHEC local health departments have been notified.

(2) **Federal Partners:** All information about the HAB event will be forwarded to the United States Food and Drug Administration (FDA) through the FDA Regional Shellfish Specialist by the SCDHEC Shellfish Program Manager directly by phone and email.

(3) **States:** SCDHEC will issue direct notification of all closures to every state that is or potentially could be affected by the HAB event by phone and email.

(4) **Shellfish Industry:** SCDHEC Shellfish Program staff will issue direct notification of all closures to South Carolina certified shellfish shippers. Certified shellfish shippers will be requested to notify all employees of the event. The SCDHEC Shellfish Program Manager will directly notify the South Carolina Department of Natural Resources – Commercial Fisheries Section by phone and email and request that all commercial shellfish harvesters be notified and that state shellfish ground permits in affected areas be suspended.

Establish Reopening Criteria including the Number of Samples over What Period of Time

All shellfish growing areas will continue to be sampled and once water sampling in the impacted area indicates that concentrations of the HAB species have fallen below the level of concern (Table 1), shellfish meats will be sampled and evaluated for toxins using NSSP approved methods and laboratories. At least two consecutive shellfish sample results collected 7 days apart (for PSP – a minimum of three samples collected over a period of at least 14 days) must demonstrate toxin concentrations are below the NSSP closure thresholds before the growing area(s) can be reopened for harvesting.

TABLE 1 – Levels of Concern for Phytoplankton Genera & Species / NSSP Closure Thresholds

Phytoplankton Genera/Species	Primary Toxin	Related Illnesses	NSSP Closure Threshold (Toxin Concentration in Shellfish Meat)	Level of Concern (Cells/mL in Water)
Karenia brevis, Chattonella spp.	Brevetoxin	Neurotoxic Shellfish Poisoning	0.8 mg/kg (20 MU/100 g) (0.8 ppm)	*K. brevis*: Presence *Chattonella*: ≥ 10,000
Alexandrium, Gymnodinium, & Pyrodinium spp.	Saxitoxin	Paralytic Shellfish Poisoning	80 µg/100 g (0.8 ppm)	≥500
Dinophysis & Prorocentrum spp.	Okadaic Acid	Diarrhetic Shellfish Poisoning	0.16 mg/kg (0.16 ppm)	*Dinophysis*: ≥ 5 *Prorocentrum*: ≥ 10,000
Pseudo-nitzschia spp.	Domoic Acid	Amnesic Shellfish Poisoning	2 mg/100 g (20 ppm)	≥ 5 µm width: ≥ 30 < 5 µm width: ≥ 100
Azadinium spinosum, Amphidoma spp.	Azaspiracid	Azaspiracid Shellfish Poisoning	0.16 mg/kg (0.16 ppm)	Presence

i.