Interstate Shellfish Sanitation Conference
Executive Board Meeting
October 6 and 7, 2014

NOTEBOOK TABLE OF CONTENTS

Interstate Shellfish Sanitation Conference

Constitution, Bylaws, and Procedures

209-2 Dawson Road
Columbia, SC 29223
Telephone 803-788-7559
Fax: 803-788-7576
Email: issc@issc.org
Website: www.issc.org

(Updated May 28, 2014)

Table of Contents

(Updated May 28, 2014)

PREFACE

The sanitary quality of shellfish shipped interstate as well as intrastate has been a matter of concern to receiving areas for many years. The value of these renewable natural resources to the early settlers was reflected in colonial legislation designed to encourage their wide use. In 1658, the Dutch Council of New Amsterdam passed an ordinance regulating the taking of oysters from the East River. Other early legislation (1715, 1730, and 1734) was designed to regulate harvesting, presumably as conservative measures to guarantee a continuing supply.

The public health problems which were associated with shellfish in the United States in the first two decades of the twentieth century brought a new dimension to natural resource utilization; i.e., shellfish could not be used as food unless of acceptable sanitary quality. The concept was clearly recognized in a Public Health Service sponsored conference in 1925. All parties seemed to recognize and accept as fact, the premises that: (1) shellfish represented a valuable natural food resource; (2) the cultivation, harvesting, and marketing of this food resource were valuable to the economy of many coastal communities; (3) a state/federal program was necessary to permit the safe use of this resource; and (4) the transmission of disease by shellfish was preventable and, therefore, not to be tolerated. Founders of the shellfish program held that instead of prohibiting use of this resource, beneficial use of the estuaries was in the best public interest, and that sanitary controls should be developed and maintained which would allow safe use.

In 1954, the Surgeon General of the United States Public Health Service called a second national conference to discuss shellfish sanitation problems. There was general agreement that, despite the profusion of technical problems, the basic concepts were sound and that it was in the public interest to maintain the program. The 1964 National Shellfish Sanitation workshop stated that survival of the shellfish industry was in the best public interest and that application of the established principles on a state-by-state basis would allow shellfish to continue to be used safely as food.

In the ensuing years, changes in the state and federal governmental organizations participating in the shellfish program and challenges to portions of the federal part of the program made participation in the program by state regulatory officials and the shellfish industry less effective. Various state programs began to diverge from established standards and the federal arm of the program appeared to be unable to retain control or re-establish uniform program application necessary to ensure the safety of shellfish for use as food. As a result, representatives of fifteen shellfish producing states met in Ocean City, Maryland, in October 1979 to investigate the problem.

This meeting established a committee to explore the alternative types of organizations that could deal with the problems and continue to ensure a viable, uniform national program. The committee, after two years of serious deliberations and numerous meetings, developed a proposal for an organization of state shellfish regulatory and industry representatives interfacing with the United States Food and Drug Administration to establish uniform basic guidelines that could be used for sanitary control of the shellfish industry. The recommended program of this proposed organization would provide regulatory authorities with reliable data on sources of high quality shellfish. The recommended

program could also be used to advantage by states and municipalities in developing sound, uniform programs to secure better shellfish supplies for their people.

In the following year the committee held meetings with representatives of the FDA, industry, and various states and further refined the proposal. A final draft was prepared and notice of a national meeting to present the proposal to state shellfish control officials for adoption was mailed.

A national meeting was convened in Annapolis, Maryland, on September 20, 1982. Representatives attended the meeting from twenty-two states, shellfish industry representatives from several east and Gulf Coast states, the United States Food and Drug Administration, and the National Marine Fisheries Service. Consideration and amendment of the Committee Proposal resulted in adoption of a Constitution, By-Laws, and Procedures on September 21, 1982, establishing a viable organization with the stated purpose of fostering and improving the sanitation of shellfish through interstate cooperation and through uniformity of state shellfish programs.

DEFINITIONS

The following definitions apply to the Constitution, By-Laws, and Procedures of the Interstate Shellfish Sanitation Conference.

(1) **INDUSTRY** - any commercial operation routinely dealing in the harvesting, processing, packaging, storage, or distribution of shellfish.

(2) **INTERPRETATION** - a written request for a clarification of a part of the National Shellfish Sanitation Program from the FDA Regional Office to FDA Headquarters, and the written response to that request from FDA Headquarters.

(3) **ISSC REGION** - geographical grouping of shellfish producing states with similar characteristics and interests, established to provide for fairly distributed representation. The ISSC Regions shall be:

Region 1	Maine, New Hampshire, Massachusetts, Rhode Island
Region 2	Connecticut, New York, New Jersey
Region 3	Maryland, Delaware, Virginia
Region 4	North Carolina, South Carolina, Georgia, Florida
Region 5	Alabama, Mississippi, Louisiana, Texas
Region 6	Alaska, Washington, Oregon, California, Hawaii

(4) **NATIONAL SHELLFISH SANITATION PROGRAM (NSSP)** - the cooperative State-FDA-Industry program for the sanitary control of shellfish. Cooperative partners may include States, the FDA, industry, tribes, other nations, and other federal agencies. The Guide for the Control of Molluscan Shellfish, including the Model Ordinance as adopted by the Interstate Shellfish Sanitation Conference replaced the NSSP Manual of Operations [effective January 1, 1998] and contains the same requirements in ordinance language.

(5) **NON-PRODUCING STATE** - any state that does not qualify as a producing state.

(6) **PARTICIPATING MEMBER** - any individual wishing to participate or receive correspondence from the Conference.

(7) **PRODUCING STATE** - a state having shellfish growing waters in its jurisdiction and having certified shellfish plants for the initial processing of shellfish.

(8) **REGISTERED VOTE** - (as used in Article XI. Section 3.b.) the maximum possible vote during the current Conference meeting, determined by counting the votes or portions of votes of all registered voting delegates.

(9) **SHELLFISH** - means all species of:

(a) Oysters, clams or mussels, whether:

(i) Shucked or in the shell;

(ii) Raw, including post-harvest processed;

(iii) Frozen or unfrozen;
(iii) Whole or in part; and

(b) Scallops in any form, except when the final product form is the adductor muscle only.

(10) **STATE** - a shellfish producing or receiving state that participates and votes in the Conference General Assembly.

(11) **STATE SHELLFISH CONTROL AUTHORITY (SSCA)** - the state agency or agencies having the legal authority to classify shellfish growing waters, to issue certificates for the interstate shipment of shellfish and to regulate harvesting, processing and shipping in accordance with the NSSP Model Ordinance [effective January 1, 1998].

(12) **UNRESOLVED ISSUE** - a disagreement or continued failure to achieve satisfactory compliance with the NSSP Model Ordinance. Unresolved issues may be between FDA and a state or between states or non-state parties.

(13) **VOTING DELEGATE** - the person designated by a state shellfish control authority to cast the agency's portion of the state vote in Conference meetings.

CONSTITUTION

OF THE

INTERSTATE SHELLFISH SANITATION CONFERENCE

ARTICLE I. ORGANIZATION

Section 1. The name of the organization shall be the "Interstate Shellfish Sanitation Conference", hereinafter referred to as the Conference.

Section 2. The Conference shall be directed by and shall be under the control of the various states, federal agencies and shellfish industry that join together to form the Conference.

ARTICLE II. OBJECTIVES

Section 1. The objective of the Conference shall be to foster and improve the sanitation of shellfish in this country and to encourage restoration of shellfish growing areas.

Section 2. The objective of the Conference shall be accomplished by:

Subdivision a. Adopting sound, uniform methods into a National Shellfish Sanitation Program that is accepted by participating shellfish control authorities.

Subdivision b. Promoting mutual respect and trust among shellfish control authorities, the shellfish industry, and consumers of shellfish.

Subdivision c. Acquainting control authorities, producers, processors, and consumers with the purpose of the Conference through the media of meetings, press releases, and publications, and by utilization of facilities and personnel of educational institutions, trade associations, shellfish control authorities, and other groups that are willing to assist in the dissemination of such information.

ARTICLE III. MEMBERSHIP AND REGISTRATION

Section 1. The membership and registration fees shall be set by the Executive Board as necessary to defray the costs of the Annual Meeting and the operating costs of the Conference.

Section 2. Membership Fees

Subdivision a. The fee for each category of membership and the membership period shall be set by the Executive Board. State membership fees will be established as necessary to provide, at a minimum, ten percent (10%) of the operating budget of the Conference. The

Executive Board will follow the guidelines of Procedure XIX. in establishing membership fees.

Subdivision b. There shall be two (2) categories of membership:
- Subdivision i. State
  - Subdivision (a) Shellfish producing states
  - Subdivision (b) Non-producing states
- Subdivision ii. Individual member

Subdivision c. The membership fees may be paid annually or biennially.

Subdivision d. The State authority membership fees shall include one membership for one Voting Delegate. Persons other than Voting Delegates shall be considered members by payment of the membership fee.

Subdivision e. The membership period shall coincide with the calendar year.

Subdivision f. Applications for membership shall be mailed at least thirty (30) days prior to the beginning of the membership period to the two (2) previous years' membership rolls.

Section 3. Registration Fees

Subdivision a. Registration fees shall include those amounts required by Article V. Section 9. of this Constitution

Subdivision b. Any person who is interested in promoting the availability of safe, wholesome shellfish may register at the Conference meeting.

Subdivision c. Persons attending and participating in a Conference meeting must first register their name, address, and affiliation with the Executive Director and pay the appropriate registration fee.

Section 4. The Board Chairperson, with the approval of the Board, shall appoint a non-voting Consumer Advisory representative. The Consumer Advisor shall serve a two (2) year term. The initial Consumer Advisory term shall be one (1) year to coincide with the Annual meeting schedule.

Section 5. Each Board member and alternate must be a member when elected. For producing state and non-producing state elections, each state may cast one (1) vote by the authorized ISSC Voting Delegates (or alternates). For industry elections, industry registrants within each state may cast one (1) collective vote. Industry may caucus among its registrants in order to determine the voting member.

Section 6. Elected Board members shall serve four-year terms. Terms of the elected Board members shall expire at the end of the voting General Assembly of the regular Annual Conference meeting.

Section 7. The Board shall elect a Chairperson and Vice-Chairperson for a two, (2) year term at the Executive Board meeting following the voting General Assembly of the regular Annual Conference meeting. New officers shall take office at the beginning of the Spring Executive Board meeting.

Section 8. The Board shall direct the Executive Director to collect membership and registration fees. The Executive Director shall pay all bills approved by the Board. The Board shall cause an audit to be made of the Executive Director's financial report annually.

Section 9. The Board shall direct the Executive Director to prepare annually a written financial report listing all receipts, expenditures, and financial balance of the ISSC for the previous year. A copy of the financial report shall be distributed to the membership at each Annual Meeting.

Section 10. The Board shall authorize the form used to tally and record votes in Board meetings and Conference meetings.

Section 11. The Board shall direct the Executive Director to prepare written minutes of all Board meetings and make copies of such minutes for the previous two years available to the ISSC membership on the ISSC website at www.issc.org.

ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES

Section 1. The Conference shall elect its Executive Board, hereinafter called the Board, in accordance with Article IV. Sections 2., 6., and 7. of this Constitution.

Section 2. The Board shall be comprised of eighteen (18) voting members selected as follows: (a) six (6) state shellfish control authority members elected from the producing states, one (1) from each of the ISSC Regions; (b) three (3) state shellfish control authority members elected at large from the non-producing states; (c) six (6) members elected from industry, one (1) from each of the ISSC Regions; (d) one (1) member designated by the United States Food and Drug Administration; (e) one (1) member designated by the National Marine Fisheries Service; and (f) one (1) member designated by the United States Environmental Protection Agency.

Section 3. The immediate past Chairperson, the Program Chairperson, the three (3) Task Force Chairpersons, the Executive Director, and the Annual Meeting Office Manager, except as otherwise provided, shall serve as non-voting members of the Board.

Section 4. The Treaty Tribes of Western Washington, signatory to the Consent Decree regarding shellfish sanitation with the State of Washington, shall have a non-voting member on the Executive Board designated by the tribal parties to the Consent Decree, whose name shall be submitted by the Northwest Indian Fisheries Commission.

Section 5. The Board Chairperson, with the approval of the Board, shall appoint a non-voting Consumer Advisory representative and a non-voting Retail Advisory representative. The Consumer Advisory representative and the Retail Advisory representative shall serve a two (2) year term. The Consumer Advisory representative term and the Retail Advisory representative term shall coincide with the Annual meeting schedule.

Section 6. Each Board member and alternate must be a member when elected. For producing state and non-producing state elections, each state may cast one (1) vote by the authorized ISSC Voting Delegates (or alternates). For industry elections, industry registrants within each state may cast one (1) collective vote. Industry may caucus among its registrants in order to determine the voting member.

Section 7. Elected Board members shall serve four-year terms. Terms of the elected Board members shall expire at the end of the voting General Assembly of the regular Annual Conference meeting.

Section 8. The Board shall elect a Chairperson and Vice-Chairperson for a two, (2) year term at the Executive Board meeting following the voting General Assembly of the regular Annual Conference meeting. New officers shall take office at the beginning of the Spring Executive Board meeting.

Section 9. The Executive Committee, at a minimum, shall consist of the Board Chairperson, Vice Chairperson, Office Manager, Program Chairperson, one Industry Executive Board member, and the immediate past Board Chairperson. The function of the Executive Committee is to provide administrative guidance to the Executive Office of the ISSC for management of daily activities. Industry representation on the Executive Committee shall be appointed by the Chairperson of the Executive Board, at each Annual Meeting, with recommendation from the industry members of the Board.

Section 10. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairperson. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference:

- Education;
- Foreign Relations;
- Model Ordinance Effectiveness Review;
- Patrol;
- Proposal Review;
- Research Guidance;
- Resolutions;
- Shellfish Restoration; and
- *Vibrio* Management.

The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Annual Meeting.

Section 11. A quorum for conducting Board business shall consist of ten (10) voting members.

Section 12. The nine-member Unresolved Issues Committee shall be comprised of a state regulatory representative from each of the six (6) regions, one (1) state regulatory representative from a non-producing state, and two (2) industry representatives at large. Should a state regulatory committee member be a representative from a state affected by an unresolved issue, the ISSC Board Chairperson shall appoint a substitute representative from another state within the same region or another non-producing state. Should an industry committee member be a representative from a state affected by an unresolved issue, the ISSC Board Chairperson shall appoint a substitute at-large industry representative. The committee Chairperson shall be a non-voting member except in the event of a tie.

Section 13. The Executive Board Chairperson shall appoint a 12-member Proposal Review Committee. The Committee will be comprised of a Chairperson, four (4) regulatory members, four (4) industry members, and a representative from the FDA, NOAA, and EPA. The Committee will review and link proposals for Conference consideration. The Committee will also provide consultation as needed to the Executive Director in assigning proposals to Task Forces.

Section 14. The Executive Board Chairperson shall appoint a sixteen (16) member *Vibrio* Management Committee. The Committee will be comprised of a Chairperson with at least two (2) industry members from the East, Gulf and West coasts and at least one (1) state regulatory from each of the ISSC regions. The Committee will also include one voting member from NOAA, one voting member from FDA, one voting member from EPA and one voting member from CDC. The Federal entities will appoint these members. Non-voting advisors will be appointed as appropriate. The Committee will assess if additional changes are needed in the NSSP Guide for the Control of Molluscan Shellfish Model Ordinance to reduce the risk of *Vibrio* illnesses. The Committee will annually review trends in *Vibrio* illnesses.

Section 15. The Executive Board Chairperson shall appoint a thirteen (13) member Model Ordinance Effectiveness Review Committee. The Committee will be comprised of a Chairperson with at least one (1) industry member from the East, Gulf, and West coasts; at least one (1) State regulatory person from each of the ISSC regions; and at least one (1) State regulatory person from a non-producing State. The Committee will also include one (1) voting member from NOAA; one (1) voting member from FDA; and one (1) voting member from EPA. The federal entities will appoint these members. This Committee will review the requirements of the NSSP Model Ordinance and identify requirements that are deemed to be ineffective. The Committee will present recommendations in proposal form to the appropriate Task Force for the deletion or modification of ineffective requirements. New requirements will not be reviewed until the fourth (4^{th}) year following the implementation date. A four (4) year waiting period will provide adequate time to determine effectiveness of new controls.

NOTE: Initially the Committee will review all of the requirements in the NSSP that have been in existence for four (4) years or more. Following the initial review, the procedure outlined above would be followed by the Committee prior to the proposal submission deadline.

ARTICLE V. DUTIES OF THE BOARD

Section 1. The Board shall manage the affairs of the Conference. The Board may act on behalf of the Voting Delegates between voting Conference meetings, in keeping with the spirit and intent of the delegates. Any decision or action taken by the Board which would require Voting Delegate approval in accordance with the remainder of this Constitution, By-Laws, or Procedures, shall be submitted as a proposal to the next voting meeting for concurrence or correction.

Section 2. The Board shall meet during each Conference meeting and after the voting General Assembly of the regular Annual Conference meeting. The Board Chairperson shall call special meetings of the Board at any time at the request of two-thirds (2/3) of its members. The Board Chairperson may call special meetings of the Board at any time, as the need arises, with the concurrence of two-thirds (2/3) of the Board members.

Section 3. The Board may retain the services of an Executive Director who shall serve as chief administrator of the Conference.

Section 4. The Board shall direct the Executive Director and the Program Chairperson in the preparation of programs for each General Assembly of the Annual Conference meeting.

Section 5. The Board shall set the time and place of each required Annual Meeting of the Conference. Special meetings of the Conference may be called as the need arises.

Section 6. In the event a vacancy occurs in its membership between elections, the Board may fill such vacancy with a qualified Conference member from the area represented to serve the unexpired term.

Section 7. If a member of the Board is unable to attend a meeting, he/she may send an elected alternate. The member shall notify the Executive Director of the substitution prior to the meeting and provide the substitute with a letter of proxy. In the event time or circumstances prevent prior notification of the alternate to the Executive Director, the letter of proxy presented to the Executive Director at the meeting shall be sufficient.

Section 8. A Board member who fails to attend two (2) consecutive Board meetings shall show cause why he/she should not resign and his/her position be declared vacant by the Executive Director. The Board meeting during each Conference meeting and the Board meeting immediately after the voting general assembly of the regular Annual

Conference meeting shall be considered as one meeting for the purposes of this Section.

Section 9. The Board shall direct the Executive Director to collect membership and registration fees. The Executive Director shall pay all bills approved by the Board. . The Board shall cause an audit to be made of the Executive Director's financial report annually. The Board shall direct the Executive Director to prepare annually a written financial report listing all receipts, expenditures, and financial balance of the ISSC for the previous year. A copy of the financial report shall be distributed to the membership at each Annual Meeting.

Section 10. The Board shall authorize the form used to tally and record votes in Board meetings and Conference meetings.

Section 11. The Board shall direct the Executive Director to prepare written minutes of all Board meetings and make copies of such minutes for the previous two years available to the ISSC membership on the ISSC website at www.issc.org.

ARTICLE VI. DUTIES OF THE BOARD CHAIRPERSON

Section 1. The Board Chairperson shall preside at all meetings of the Board and during Conference meetings, except as provided for in Article VII. of this Constitution.

Section 2. The Board Chairperson, with the approval of the Board, shall appoint committees as directed by the Conference, the Board, the Constitution, or the By-Laws.

Section 3. The Board Chairperson, with the approval of the Board, shall appoint the Task Force Chairpersons, Vice-Chairpersons, and Members as outlined in Article I., Section 2. and Section 3. of the By-Laws of the Conference.

Section 4. The Board Chairperson, with the approval of the Board, shall appoint Task Force consultants as outlined in Article II. Section 1. of the By-Laws of the Conference.

Section 5. The Board Chairperson, with the approval of the Board, shall appoint a Program Chairperson and an Annual Meeting Office Manager.

Section 6. The Board Chairperson, with the approval of the Board, shall appoint an Unresolved Issues Committee.

Section 7. The Board Chairperson, with the approval of the Board, shall appoint Executive Board advisors.

ARTICLE VII. DUTIES OF THE VICE-CHAIRPERSON

Section 1. In the event the Board Chairperson is unable to attend any meeting of the Board or Conference, the Board Vice-Chairperson shall act as Board Chairperson at the meeting.

Section 2. When acting as Board Chairperson as provided in Section 1. of this Article, the Vice-Chairperson shall perform all the necessary duties for the Conference as outlined in Article VI. of this Constitution.

ARTICLE VIII. DUTIES OF THE EXECUTIVE DIRECTOR

Section 1. The Executive Director shall serve as chief administrator of the Conference and shall serve as a non-voting member of the Executive Board. The Executive Director shall conduct the affairs of the Conference and shall implement the decisions and policies of the Board and voting delegates.

Section 2. The duties of the Executive Director shall be:

Subdivision a. Coordination of ISSC external affairs, specifically interacting with other designated organizations, federal and State government agencies, Congressional committees and staff, State legislative bodies, shellfish and other food-related industries, and other entities whose work or interests affect public health issues relating to the consumption of molluscan shellfish;

Subdivision b. Advisement of the Board concerning prioritization of external areas requiring ISSC involvement. Assistance in development of long-range goals and strategies;

Subdivision c. Preparation and oversight of position papers or other public policy documents for approval by the Board. Preparation of routine ISSC correspondence;

Subdivision d. Spokesperson for ISSC providing or arranging testimony or dialogue on ISSC issues and positions;

Subdivision e. Management of the Executive Office and supervision of Executive Office staff;

Subdivision f. Management of the fiscal affairs of ISSC in cooperation with the Executive Committee.

Section 3. The Executive Director shall plan and arrange all Conference meetings.

Section 4. The Executive Director may retain the services of a parliamentarian to rule on matters of parliamentary procedure at Board meetings and during Conference meetings.

Section 5. The Executive Director, with the approval of the Board, may retain clerical assistance as needed.

Section 6. The Executive Director shall record the minutes of each meeting of the Board and the Conference.

Section 7. The Executive Director shall tally and record all voting of the Board and of the Conference on a form authorized by the Board.

Section 8. The Executive Director shall pay bills as directed by the Board. A receipt shall be obtained for all disbursements and shall be made a part of Board records.

Section 9. The Executive Director shall accomplish the requirements outlined in Article XI. Section 3. Subdivision d., Section 3. Subdivision e., Section 3. Subdivision f., and Section 3. Subdivision g. of this Constitution.

Section 10. The Executive Director shall mail a copy of the tentative program sixty (60) days prior to the Conference meeting to each registrant of the previous Conference meeting and to any State authority or shellfish industry member or representative who so requests and shall prepare and distribute programs at each Conference meeting.

Section 11. The Executive Director shall notify the appropriate shellfish control authorities in each state, at least ninety (90) days prior to each Conference meeting, of the time and place of the meeting and what proposals are to be voted on under the heading of unfinished business.

Section 12. The Executive Director shall notify the United States Food and Drug Administration, National Marine Fisheries Service, and the United States Environmental Protection Agency at least one hundred twenty (120) days prior to each Conference meeting of the time and place of the meeting so that FDA can publish this information in the Interstate Shellfish Shippers List (ICSSL) at least ninety (90) days prior to the meeting.

ARTICLE IX. DUTIES OF THE PROGRAM CHAIRPERSON

Section 1. The Program Chairperson shall assist the Executive Director in planning and arranging for all Conference meetings.

Section 2. The Program Chairperson shall serve as a non-voting member of the Executive Board.

ARTICLE X. DUTIES OF ANNUAL MEETING OFFICE MANAGER

Section 1. The Annual Meeting Office Manager shall assist the Executive Director in planning, establishing, and managing the operations center for the Annual Meeting.

Section 2. The Annual Meeting Office Manager shall serve as a non-voting member of the Executive Board.

ARTICLE XI. RULES OF ANNUAL CONFERENCE MEETINGS

Section 1. Except for special meetings, as provided for in Article V., Section 5. of this Constitution, the Conference will convene a meeting annually and will rotate the meeting location among the different ISSC Regions of the country.

NOTE: The next Biennial Meeting will be held in 2015 and subsequent meetings will then be held annually beginning in 2016.

Section 2. Conference meetings shall include the following:

Subdivision a. Registration - all attendees must register;
Subdivision b. Call to order by the Board Chairperson;
Subdivision c. Roll call of the states and announcement of the name of the delegates who will vote for each state in General Assembly;
Subdivision d. Audit report;
Subdivision e. Unfinished business;
Subdivision f. Subcommittee and Committee meeting;
Subdivision g. Task Force meetings;
Subdivision h. Election of Board members;
Subdivision i. Program, new business, and committee reports;
Subdivision j. Installation of new Board members;

Section 3. Business Rules of Conference Meetings

Subdivision a. Robert's Rules of Order shall prevail, unless specific rules are established by the Conference.

Subdivision b. Each shellfish producing state shall be entitled to one (1) full vote in the Conference meeting general assembly and each non-producing state shall be entitled to one (1) vote in the Conference meeting general assembly with the exception of issues involving Task Force I recommendations. Non-producing states shall be entitled to one-half (1/2) vote on proposals involving Task Force I recommendations. In states where elements of the NSSP are administered by different shellfish control agencies, each agency shall have an appropriate portion of the vote, or at the option of the state, the vote may be combined and cast by the voting delegate of the single shellfish control agency selected by the state. Membership fees must be paid by the participating state in order to exercise voting privileges.

Subdivision c. Only a registrant at the Conference meeting who is a representative of a state shellfish control authority is entitled to be a voting delegate. Each voting delegate at the meeting may cast a vote only for his/her own state agency, except when the state vote

has been combined in accordance with Article XI. Section 3.b. of this Constitution and assigned to his/her agency.

Subdivision d. Ninety (90) days prior to a meeting, the Executive Director shall send to the office or offices of all appropriate shellfish control authorities in each participating state notice of the forthcoming meeting. Each notice shall include a copy of Article XI. Section 3.b., Section 3.c., and Section 3.d. of this Constitution. Each authority shall report in writing on forms provided within thirty (30) days to the Executive Director the following: (1) its official designated responsibility, (2) the name of the delegate and alternate or alternates and the agency represented, and (3) the portion of the vote the delegate is to cast.

Subdivision e. In the event the sum total of the portions of the vote designated for an individual state's delegates exceeds the amount authorized for that state, the Executive Director shall reject, void, and return the reports to the authorities for correction so that they are in compliance with Article XI. Section 3.b. of this Constitution. Such revision shall be submitted at least thirty (30) days before the meeting.

Subdivision f. A qualified Voting Delegate who must leave the meeting may transfer his/her voting privileges to another qualified registrant from his/her state. The transfer must be presented in writing to the Credentials Committee signed by the departing voting delegate. Upon approval, the Credentials Committee Chairperson shall notify the Executive Director of the transfer of voting privilege.

Subdivision g. Each state Voting Delegate shall record his/her name with the Executive Director and shall cast his/her vote in the Conference meeting General Assembly when the state's name is called by announcing "yes" or "no" for the delegate's appropriate portion of the vote.

Subdivision h. Voting in the Conference meeting General Assembly shall be recorded as "yes" or "no".

Subdivision i. In case of a roll call vote, if a state's representative wishes to caucus, the delegates may pass for the purpose of caucusing when the state's name is called and then shall vote when the second roll is called.

Subdivision j. To adopt in Conference meeting general assembly:

- Subdivision i. A quorum must be present.
- Subdivision ii. A quorum shall consist of two-thirds (2/3) of the registered vote at the Conference meeting.
- Subdivision iii. In order to adopt a new Procedure, a simple majority vote is required for passage. In order to change an existing Procedure in any way, a two-thirds (2/3) majority vote is required for passage.

Subdivision k. Recommendations from a Task Force can be adopted as written, editorially amended to be correct, or consistent with other language in the NSSP Model Ordinance, Constitution, By-Laws, or Procedures, rejected by voting "No Action", or referred back to a Task Force or Committee. The Executive Director will determine whether it is referred to a Task Force or Committee.

ARTICLE XII. AMENDMENTS

Section 1. This Constitution may be amended at a duly called Conference meeting, the delegates having had sixty (60) days' notice from the Executive Director of proposed amendments. Adoption of an amendment to the Constitution shall require at least a two-thirds (2/3) majority vote.

Section 2. Amendments to the Constitution will become effective at the close of the Conference meeting at which they are adopted.

ARTICLE XIII. PROCEDURE FOR THE SUBMISSION OF PROPOSALS

Section 1. The Executive Director shall provide each registrant of the preceding Conference meeting at least one hundred sixty-five (165) days prior to the next Conference meeting with forms on which proposal for problems are to be submitted to the Executive Director for assignment to the appropriate Task Force.

Section 2. All proposals must be submitted to the Executive Office no later than one hundred twenty (120) days prior to the Conference meeting.

Section 3. Proposals submitted by any Conference participants requiring Conference action are to be referred to the Executive Director for assignment to the appropriate Task Force.

Section 4. The Executive Director shall review and assign all problems or proposals received for Task Force and Conference deliberation. Problem or proposal assignment shall be made according to subject matter and in accordance with Article XIII. Section 5., Section 6., and Section 7. of the Constitution of the Conference.

Section 5. Task Force I - Growing Areas: all proposals submitted to the Conference dealing with the classification or patrol of shellfish growing waters, relaying, training and research, or similar items concerning growing areas shall be assigned to Task Force I by the Executive Director.

Section 6. Task Force II – Harvesting, Handling, and Distribution: all proposals submitted to the Conference dealing with the sanitation of harvesting, depuration, processing, labeling, transporting, storage, fill or content, training and research, or similar items concerning processing and distribution shall be assigned to Task Force II by the Executive Director.

Section 7. Task Force III - Administration: all proposals submitted to the Conference dealing with Conference agreements, memorandums of understanding, complaints and challenges of reciprocity and program evaluations, or similar items, or items not specifically relating to Task Force I or II shall be assigned to Task Force III by the Executive Director.

Section 8. The Executive Director shall provide the appropriate shellfish control authorities in each state and all members, at least ninety (90) days prior to each Conference meeting, with the proposals to be discussed under the heading of Unfinished Business or New Business.

Section 9. Proposals submitted after the deadline, established in Article XIII Section 2. of the Constitution, will be reviewed and may be accepted by the Executive Board for Task Force Consideration. The Executive Board will use the following criteria in accepting late proposals.

Subdivision a. Why is the proposal being submitted after the deadline?

Subdivision b. Was the information available prior to the deadline?

Subdivision c. What is the criticality of the proposal to the safety of molluscan shellfish or the future of the ISSC?

Subdivision d. Does the proposal involve an NSSP Guide for the Control of Molluscan Shellfish change or an ISSC administrative change?

Section 10. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid.

BY-LAWS

OF THE

INTERSTATE SHELLFISH SANITATION CONFERENCE

ARTICLE I. TASK FORCES

Section 1. There shall exist three (3) Task Forces in the Conference to provide for continuity of action in carrying out the objectives of the Conference. The Task Forces shall be known as Task Force I, Task Force II, and Task Force III.

Section 2. Each Task Force shall have a total voting membership of eight (8) members to be appointed by the Board Chairperson with the approval of the Board.

Subdivision a. Four (4) of the voting members shall be selected from state shellfish control authorities and four (4) shall be selected from industry providing that each ISSC Region shall be represented by at least one (1) Task Force member, either industry or regulatory. The Chairperson (the ninth voting member who will vote only in case of a tie vote) shall alternately be selected from a state shellfish control authority and from industry as outlined in Article I., Section 3. of the By-Laws.

Subdivision b. Three (3) of the state shellfish control authority members shall be from producing states and one (1) shall be from a non-producing state, except for Task Force I where at least four (4) shellfish control authority members shall be from producing states. Prior to the March Board meeting, the industry and regulatory Board member from each region may submit a list of Task Force nominees of up to three (3) candidates each per Task Force to the Board Chairperson. The Board Chairperson shall appoint a member from each ISSC Region to each Task Force from the list of candidates submitted. The Board shall approve the candidates selected. In the absence of any nominees submitted from a region, the Board Chairperson, with Board approval, shall appoint the Task Force member.

Section 3. The Board Chairperson, with approval of the Board, shall appoint a Chairperson and Vice-Chairperson for each Task Force.

Subdivision a. If the Task Force Chairperson represents a state shellfish control, the Vice-Chairperson shall be an industry representative.

Subdivision b. At the end of the Task Force Chairperson's term of office, the Vice-Chairperson will become Chairperson and a new Vice-Chairperson will be appointed who represents the same segment of the Conference as the outgoing Task Force Chairperson.

Section 4. The Task Force Chairperson and Vice-Chairperson shall serve for a four (4) year period, i.e., through two (2) consecutive Conference Annual meetings. Task Force members may not serve more than two (2) consecutive Annual Meetings on the same Task Force.

Section 5. A quorum for conducting Task Force business shall consist of five (5) voting members.

Section 6. Each Task Force shall deliberate all proposals during the times specified at the Conference meeting. Each Task Force Chairperson shall report the actions recommended by his/her respective Task Force to the voting delegates at the Conference under the heading of New Business for final Conference consideration. Any "No Action" recommended by a Task Force shall contain the reasons for the "No Action" recommendation.

Section 7. If a Task Force member is unable to attend the Annual Meeting, he/she shall notify the Executive Director prior to the first Executive Board meeting. The Board Chairperson, with approval of the Board, shall appoint a replacement that represents the same segment of the Conference as the member who is unable to attend to serve the remainder of the unexpired term. The Board Chairperson will confer with Board members from the affected region before appointing a replacement.

ARTICLE II. TASK FORCE CONSULTANTS

Section 1. The Board Chairperson shall appoint a consultant for each Task Force from the Board.

Section 2. FDA, EPA, and NMFS may provide a consultant for each Task Force.

Section 3. Consultants will have no voting rights in Task Force action but will attend Task Force deliberations to offer advice as needed.

ARTICLE III. AMENDMENTS

Section 1. These By-Laws may be amended at a duly called Conference meeting, the Delegates having had sixty (60) days' notice from the Executive Director of proposed amendments. Adoption of an amendment to the By-Laws shall require at least a two-thirds (2/3) majority vote.

Section 2. Amendments to the By-Laws will become effective at the close of the Conference meeting at which they are adopted.

PROCEDURES

OF THE

INTERSTATE SHELLFISH SANITATION CONFERENCE

PROCEDURE I. PURPOSE

The Interstate Shellfish Sanitation Conference (ISSC) is intended to foster and improve the sanitation of shellfish through cooperation and through uniformity of state shellfish programs.

PROCEDURE II. PROGRAM

Section 1. To achieve its goal, the ISSC will adopt a NSSP Guide for the Control of Molluscan Shellfish for sanitary control of shellfish that is adequate to ensure that the shellfish produced in a state that complies with these guidelines will be safe and sanitary. This NSSP Guide for the Control of Molluscan Shellfish shall be called the National Shellfish Sanitation Program (NSSP).

Section 2. The ISSC shall adopt an NSSP Guide for the Control of Molluscan Shellfish as the NSSP, effective January 1998.

PROCEDURE III. RESPONSIBILITIES OF THE STATE

Section 1. The state shall have adequate laws and regulations to provide a legal basis for sanitary control of all interstate phases of the shellfish industry.

Section 2. The state shellfish growing area classification authority shall forward the classification of shellfish growing waters in the state to the appropriate Food and Drug Administration (FDA) Regional Office. The most recent classification shall be reported. When the classification of growing waters changes, the most recent classification shall apply and shall be submitted to FDA. The state shellfish growing area classification authority shall keep current the classification of all growing waters within its state.

Section 3. The State Shellfish Sanitation Control Authority of the shipping state shall certify the results of inspections of each interstate shellfish shipper meeting NSSP requirements to the FDA headquarters office for inclusion in the Interstate Certified Shellfish Shippers List (ICSSL), with copies to the appropriate FDA Regional Office. The certification inspection report, together with other pertinent information, shall be forwarded with the appropriate FDA form number FDA 3038b. The most recent certification status of a shipper shall be reported. When the sanitation compliance status of a listed shipper changes, as a result of a new inspection made with the twelve (12) month eligibility period, the most recent status shall apply and shall be submitted

to FDA. When a certified interstate shellfish shipper changes status because of certificate revocation, the shipping state shall immediately notify the FDA headquarters office, all known receiving states, the ISSC, and the appropriate FDA Regional Office. Receiving states shall immediately notify shipping states in writing with a copy of irregularities in shellfish received, which may raise questions concerning the source or quality of the product.

Section 4. The State Shellfish Control Authorities shall accept responsibility for having trained personnel to implement the state programs. Methods should be developed so that personnel who have completed the training can demonstrate proficiency at appropriate intervals.

Section 5. Shellfish growing area patrol activities shall be carried out by an enforcement authority designated by the state in any productive shellfish growing areas failing to meet the approved area criteria of the NSSP.

Section 6. All phases associated with the relaying of shellfish from closed areas to approved areas shall be under the immediate supervision of the appropriate responsible state shellfish control authority.

Section 7. Depuration may be permitted only under the effective supervision of the state shellfish control authority(ies).

Section 8. Laboratories shall be provided and staffed to effectively support the state shellfish program. Sample analysis shall be performed in accordance with the latest approved edition of the APHA, AOAC, or ISSC approved methods.

PROCEDURE IV. RESPONSIBILITIES OF THE FDA

Section 1. The FDA should promote uniformity among FDA personnel through a national shellfish-training program, which will be conducted at least every three (3) years. Methods should be developed so that personnel who have completed the course can demonstrate proficiency in lieu of attending the course at subsequent intervals. The FDA should administer an ISSC approved training course at least every three (3) years for state shellfish control personnel. The FDA should evaluate and ensure the uniformity of methods of state shellfish laboratory personnel who are responsible for the operation of the state laboratories. The FDA annual state program evaluation should include: a listing and the date of most recent training of the state shellfish control personnel who have completed the appropriate training, a list of FDA personnel who have completed the appropriate training, and a list of state shellfish laboratory personnel whose competence in interpreting and evaluating shellfish laboratory methods has been demonstrated to and evaluated by the FDA.

Section 2. The FDA should publish the ICSSL monthly. The ICSSL should include certification of shellfish shippers as submitted by the states.

Section 3. The FDA should prepare an annual evaluation of the shellfish program of each state in accordance with the Procedures of the NSSP. This evaluation should consider the program as a whole and should also specifically address the legal authority, the classification of shellfish growing waters, the shellfish sanitation control and certification, personnel training, patrol, relaying, depuration and laboratory phases of the program, and the status of state authorities Memorandums of Understanding. The state evaluation prepared by the Regional Shellfish Specialist should be reviewed and discussed with the appropriate state shellfish officials prior to submission to FDA headquarters.

Section 4. Interpretations of the FDA recommended National Shellfish Sanitation Program and FDA evaluation procedures should be furnished periodically to the state shellfish control authorities. Administrative procedures developed by the FDA should be drafted and forwarded to the ISSC for review and comment prior to their adoption. The ISSC should stand ready to deal with such problems on a continuing basis.

PROCEDURE V. GUIDELINES

The NSSP as adopted by the ISSC and the FDA, without footnotes except as the Conference may adopt, shall be used as the basic guidelines for the classification of shellfish growing waters and the basic sanitation guidelines in making shellfish sanitation certification inspections of interstate shellfish shippers. The Conference discourages the use of separate guidelines for intrastate shellfish shippers. Shellfish from any state participating in the ISSC should be accepted for sale in any other member state under the principles of reciprocity, provided the state's program is in compliance with the NSSP. Such states shall be indicated on the ICSSL. For the purpose of the NSSP and ISSC in total, the District of Columbia shall be considered as a state with all the rights, duties, responsibilities, and privileges of a state.

PROCEDURE VI. GROWING WATERS CLASSIFICATION

The state shellfish classification authority shall survey and classify the shellfish growing waters of the state in accordance with the methods outlined in the NSSP. Classification of shellfish growing waters shall be made by qualified state shellfish classification personnel who have successfully completed training. Classification shall be reappraised at least every twelve (12) months, a complete resurvey shall be completed at least every three (3) years, and a comprehensive sanitary survey at least every twelve (12) years.

PROCEDURE VII. SHIPPER CERTIFICATION

A shipper desiring classification of his plant for the purpose of interstate shipment of shellfish shall submit a request to the state shellfish sanitation control authority in his own state. Shellfish sanitation certification inspections shall be made by qualified state shellfish sanitation control personnel who have completed the appropriate training. State shellfish sanitation certification inspections shall be

made at least annually. The names, certification numbers, and locations of all certified interstate shippers shall be published monthly in the ICSSL.

PROCEDURE VIII. BILL OF LADING AND LABELING

Section 1. All interstate shipments of shellfish must be accompanied by copies of a bill of lading which includes the following information: (a) shipper's name, address and certification number; (b) point of origin of shipment; (c) quantity of product; (d) type of product; (e) date of shipment. All entries on bills of lading shall be legible. When the interstate shipment is derived from more than one shipper, separate bills of lading for each of the sources shall accompany the shipment.

Section 2. All individual containers of shellfish in interstate shipment shall be labeled in accordance with applicable FDA and NSSP requirements.

PROCEDURE IX. PROCEDURES FOR HANDLING COMPLAINTS AND CHALLENGES REGARDING THE ADEQUACY OF CERTIFICATION CONTROLS

Section 1. Complaints from any state or non-state party regarding possible non-conformities in a producing and/or shipping state shall be handled as follows:

Subdivision a. Only complaints regarding the sanitary quality and effectiveness of public health controls shall be covered under this procedure.

Subdivision b. Complaints shall be made in writing to the state shellfish control authority as listed in the ICSSL, with a copy to the appropriate FDA Regional Office.

Subdivision c. The complaint shall provide specific and complete factual information concerning all items not in conformity and shall specifically verify that all sampling and testing has been conducted in accordance with the NSSP.

Subdivision d. The state shellfish control authority shall make an investigation of the complaint within twenty (20) working days of receipt, promptly notify the complainant in writing of the findings and any actions being taken, and provide a copy to the appropriate FDA Regional Office.

Subdivision e. Upon receipt of the response or upon the failure to receive a response within thirty (30) days, the complainant may request in writing to the ISSC Board Chairperson that further investigation by FDA be conducted. FDA may also undertake further investigation at their own initiative.

Subdivision f. FDA shall provide a written report of its findings or the status of the complainant within thirty (30) days to the parties involved and the ISSC Board Chairperson.

Subdivision g. If FDA's investigation does not lead to a satisfactory resolution of the problem, the problem shall be handled as an unresolved issue according to Procedure IX. Section 3.

Section 2. When an FDA field inspection or an overall program evaluation indicates a state program is not meeting the minimum requirements of the NSSP Model Ordinance, the following actions shall be taken:

Subdivision a. FDA shall provide written notification to the state shellfish control authority of the item(s) requiring action with supporting documentation and recommendations as appropriate.

Subdivision b. The state shall investigate the item(s) and provide a written response within thirty (30) days that it has been corrected, that a corrective action plan has been developed and will be implemented within a specific time frame, or that it disagrees with FDA's finding. The state shall provide supporting documentation regarding any disagreements. FDA shall review the materials submitted by the state and respond to the state within thirty (30) days.

Subdivision c. When a state does not disagree with FDA findings, but does disagree with an FDA report, the state shall provide written notification to FDA of the areas of disagreement with supporting documentation and recommendations as appropriate. FDA shall review the information submitted and provide a written response within thirty (30) days that it agrees and the report has been corrected, that it agrees but the report cannot be corrected, or that it disagrees with the state. FDA shall provide supporting documentation regarding any inability to correct a report or any disagreement. The state shall review the materials submitted by FDA and respond to FDA within thirty (30) days.

Subdivision d. If corrective action is taken by the state or by the FDA or a mutually agreed upon action plan is developed and implemented, no action by the Conference will be necessary.

Subdivision e. If FDA considers the action (or lack of action) taken by the state to be inadequate to resolve the item(s), or if the state disagrees with FDA's findings or response, it shall be considered an unresolved issue. FDA or the state shall notify the ISSC Executive Director who shall consult with both the state and FDA and prepare recommendations, which will be submitted to the Board with the unresolved issue. The referred unresolved issue shall be handled according to Procedure IX., Section 3. FDA may also take any actions it considers appropriate to deal with any adulterated product.

Section 3. After receipt of an unresolved issue, the Executive Director shall immediately send the unresolved issue to the Executive Board. Within thirty (30) days of receipt of the unresolved issue by the Executive Director, the Executive Board shall take one (1) of the following actions:

Subdivision a. Resolve the issue on their own initiative.

Subdivision b. Refer the matter to the Unresolved Issues Committee.

Section 4. When an issue has been referred, the Unresolved Issues Committee shall convene a meeting, giving all involved parties an opportunity to participate. The Committee shall review the issue, and considering input from involved parties, submit its recommendations to the Executive Board.

Section 5. The following list of deficiencies and sanctions shall serve as a guide for actions should the Executive Board confirm the findings of the FDA evaluation.

Subdivision a. State program deficiencies, which may result in ISSC sanctions, are as follows:

Subdivision i. Administrative - Inadequate State Laws/ Regulations to Enforce the Program

Subdivision ii. Growing Areas

- Subdivision (a) Failure to properly classify.
- Subdivision (b) Failure to close in an emergency situation.
- Subdivision (c) Repeated failure to comply with conditional management plans.
- Subdivision (d) Lack of sanitary survey and supporting documentation justifying classifications.
- Subdivision (e) Lack of Biotoxin contingency plan.
- Subdivision (f) Failure to comply with contingency plans.

Subdivision iii. Plant Sanitation

- Subdivision (a) Failure to have a standardization officer.
- Subdivision (b) Certification of plants by non-standardized inspector.
- Subdivision (c) Failure to take action on critical deficiencies.
- Subdivision (d) Significant differences between state vs. state/FDA inspections.
- Subdivision (e) Repeated Critical and Key items at significant number of firms.
- Subdivision (f) Inadequate state laws/ regulations to enforce program.

Subdivision iv. Other Program Areas

- Subdivision (a) Inadequate tagging and records by shellfish dealers.
- Subdivision (b) Refusal to participate/provide cooperation in FDA program evaluations.
- Subdivision (c) Failure to control relaying.

Subdivision b. The following actions shall be taken by the Executive Board as appropriate:

- Subdivision i. Meeting(s) with responsible state officials to express ISSC concern about the unresolved issue and to develop an acceptable action plan.
- Subdivision ii. A letter to top state program administrators, including the governor, expressing ISSC concern regarding state program deficiencies.
- Subdivision iii. Notification to ISSC members of the unresolved issue for their information.
- Subdivision iv. Recommendation to FDA to include a notice in the ICSSL regarding the unresolved issue.
- Subdivision v. Recommendation to the state shellfish control authority to remove affected dealers from the ICSSL.
- Subdivision vi. Recommendation to FDA to remove all certified dealers from future ICSSL publications.
- Subdivision vii. Notification to all states and other appropriate authorities describing the unresolved issue and that action against products from a state with significant control problems may be appropriate for their consideration.
- Subdivision viii. A letter to FDA expressing ISSC concern regarding the position of FDA.

PROCEDURE X. PROCEDURE FOR HANDLING ISSC SUMMARY OF ACTIONS

Unless explicitly specified otherwise by a vote of the voting delegates, recommended changes in the NSSP or Procedures shall be implemented in accordance with the following schedule:

Section 1. The Summary of Actions for the Annual meeting shall be forwarded to FDA within sixty (60) days of the close of the Annual meeting.

Section 2. FDA will review the actions of the ISSC and within sixty (60) days of the receipt will notify the Board Chairperson of the ISSC of which actions conflict with existing federal laws, regulations or policies. NSSP changes, with which FDA concurs, will be effective upon posting on the FDA website unless otherwise stated in the Summary of Actions or in the NSSP Model Ordinance. The Task Force may recommend a specific implementation date.

Section 3. For those actions which FDA feels conflict with existing federal laws, regulations or written policies or when a federal law, regulation or written policy does not address the issue, a written decision made by the Director, FDA Office of Seafood, along with supporting rationale, will be provided to the ISSC Chairperson within sixty (60) days of receipt of the Summary of Actions.

Section 4. The ISSC Chairperson will refer those actions which FDA feels conflict with existing federal laws, regulations, or written policies with FDA's rationale, to the Executive Board for further discussion or referral to the next Annual meeting for reconsideration.

PROCEDURE XI. PROCEDURE FOR HANDLING RESOLUTIONS

Section 1. The Board Chairperson, with approval of the Board, shall appoint a four-member Resolutions Committee. Membership shall consist of one member from regulatory, one member from industry, one representative from FDA, and one member from NMFS. The appointment of the Committee and the duties of the Committee will be as outlined in the ISSC Constitution, By-Laws, and Procedures.

Section 2. The objective of the Resolutions Committee shall be to review all proposed resolutions with respect to criteria for content and format and for adherence to time frames for submission and posting to permit adequate review by all Conference participants prior to the final Voting General Assembly. Depending on circumstances and timing, resolutions may be submitted by any Conference member for consideration by the General Assembly or by the Board at interim meetings.

Section 3. For the purpose of resolution procedures, there shall be two types of resolutions.

Subdivision a. Housekeeping resolutions are routine resolutions for acknowledging accomplishments or recognition of services, such as hotel staff and volunteers, for activities performed. Housekeeping resolutions may be submitted at any time prior to the voting of the General Assembly.

Subdivision b. Substantive resolutions are relevant to the objectives to the ISSC. Substantive resolutions shall be submitted to the Resolutions Committee Chairperson no later than two days prior to the issuance of the final Task Force Reports. Copies of the resolutions, including Resolution Committee recommendations, shall be included with the Task Force Reports when they are distributed for membership consideration.

Section 4. There are two prescribed criteria for resolutions.

Subdivision a. Resolutions shall not propose changes in major ISSC policies, the Constitution, By-Laws, or Procedures or the NSSP. These changes are considered Proposals and must be submitted as outlined in Article XIII. of the Constitution for consideration by Task Forces.

Subdivision b. Resolutions shall be submitted uniformly using a standard ISSC Resolution Form.

Section 5. The Resolutions Committee, in reviewing the submitted resolution, may:

Subdivision a. Make editorial changes (grammatical, spelling, or format only); and

Subdivision b. Make substantive changes (must discuss with submitter)

Section 6. The Resolutions Committee shall make recommendations that may include:

Subdivision a. Referral to the General Assembly and/or the Board for consideration; and

Subdivision b. Referral to the Board for assignment to a Task Force for appropriate action.

The Committee must provide in writing its reason for the action it has taken.

PROCEDURE XII. PROCEDURE FOR HANDLING AND DISSEMINATING INTERPRETATIONS OF THE NSSP GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH BY FDA.

Section 1. A request for Interpretation must be submitted to FDA Headquarters (Office of Food Safety) through either an FDA Regional Office or the ISSC Executive Director according to the following routes:

Subdivision a. The interpretation request is submitted to the Office of Food Safety following the administrative chain of communication from industry to the State and, to the FDA Regional Office; or

Subdivision b. The interpretation request is submitted to the ISSC Executive Director by industry, a State, or the general public. The ISSC forwards the interpretation request to Office of Food Safety for a response.

Section 2. The interpretation request submitted to Office of Food Safety must be written and include the following:

Subdivision a. The question to be interpreted. Clearly state what the issue(s) is and include the NSSP Guide for the Control of Molluscan Shellfish reference(s) that is unclear and requires interpretation. Include any NSSP Guide for the Control of Molluscan Shellfish references related to the question.

Subdivision b. Who is requesting the interpretation? Give the name, state, area of interest (i.e., an industry person who operates an oyster shucker/packer operation, a State Shellfish Standardization Officer, etc.) and his/her address and phone number.

Subdivision c. The background surrounding the interpretation request. It is very important to understand the circumstances, motivation, and purpose for an interpretation to put it into context.

Subdivision d. An opinion on resolving the problem. Include ideas on what the Interpretation should be. This includes what the NSSP Guide for the Control of Molluscan Shellfish means, the intent of the NSSP Guide for the Control of Molluscan Shellfish, how appropriate reference (CFR, EPA Guidance Document, etc.) should be interpreted.

Section 3. Within seven (7) days, the Office of Food Safety will acknowledge receipt of the letter to the requestor and FDA's Division of Federal and State Relations (DFSR).

Section 4. All requests for interpretations must be sent to the Office of Food Safety.

Subdivision a. Within sixty (60) days of acknowledgment of the letter, the Office of Food Safety will provide a draft proposal to the FDA Regional Offices, the ISSC Executive Director, and DFSR for comment. The ISSC Executive Director shall distribute the draft proposal to the requestor and ISSC members from states, industry, and the general public.

Subdivision b. An additional thirty (30) days may be permitted for draft development if circumstances warrant. The requestor must be notified of the additional development time.

Section 5. Comments on the Draft Interpretation.

Subdivision a. The FDA Regional Offices, ISSC Executive Director, and DFSR have thirty (30) days from receipt to comment on the draft proposal to the Office of Food Safety. The ISSC Executive Director is responsible for receiving, consolidating, and forwarding to the Office of Food Safety comments from ISSC members from states, industry, and the general public.

Subdivision b. The FDA Regional Offices, ISSC Executive Director, and DFSR may request, in writing to the Office of Food Safety, an additional thirty (30) days to comment on the draft proposal.

Section 6. Action on Draft Interpretation Comments.

Subdivision a. The Office of Food Safety has thirty (30) days from receipt of comments to complete the final interpretation by:

Subdivision i. Incorporating the comments and issuing a final interpretation; or

Subdivision ii. Issuing the final interpretation without revision.

Subdivision b. FDA may request an additional thirty (30) days for issuance of the final interpretation if circumstances warrant. The requestor and ISSC Executive Director must be notified of the additional development time.

Section 7. The Office of Food Safety shall disseminate final interpretations to the ISSC and DFSR for dissemination as follows:

Subdivision a. Upon receipt of the final interpretation, the ISSC Executive Director shall distribute it to the requestor and ISSC members from states, industry, and the general public.

Subdivision b. Upon receipt of the final interpretation, DFSR shall distribute it to the FDA Regional Offices and the Office of Food Safety.

Subdivision c. Final interpretation shall be incorporated into the NSSP Guide for the Control of Molluscan Shellfish.

PROCEDURE XIII. PROCEDURE FOR INCORPORATION OF APPENDICES INTO THE NSSP MODEL ORDINANCE.

Reference materials related to Satisfactory Compliance will be included in the NSSP Model Ordinance. All other reference materials will be referenced by title only.

PROCEDURE XIV. PROCEDURE FOR ADDRESSING PATHOGENS AND DELETERIOUS SUBSTANCES NEWLY RECOGNIZED IN SHELLFISH.

Section 1. Issues or concerns regarding pathogen(s) or deleterious substances newly recognized in shellfish, which may not be presently addressed in the NSSP submitted to the Conference for action, shall be immediately referred to the Pathogen Review Committee. The committee shall review the issue or concern, gather information, and provide a written report and recommendation to the Executive Board or Task Force for appropriate action. The intent of this procedure is to provide a base of knowledge in an expeditious manner for effective action by the ISSC. The written report shall include:

Subdivision a. Characterization of the pathogen or deleterious substance. Characterization shall address, as a minimum, the following:

- Subdivision i. The illness and symptoms
- Subdivision ii. Dose/response relationship
- Subdivision iii. Route of transmission
- Subdivision iv. Incidence of illness
- Subdivision v. Population affected
- Subdivision vi. Source of pathogen
- Subdivision vii. Pollution level association
- Subdivision viii. Geographic scope
- Subdivision ix. Type of shellfish implicated

Subdivision b. A detailed summary of the literature search conducted by the committee. The search shall include, as a minimum, the following:

- Subdivision i. Published literature
- Subdivision ii. Grey literature
- Subdivision iii. White papers
- Subdivision iv. Personal communication

Subdivision c. Recommendation on the adequacy of present NSSP or other controls in addressing the pathogen or deleterious substance.

Subdivision d. Recommendation of additional NSSP controls or alternative controls if appropriate.

Subdivision e. Recommendation of additional data or information needs critical to development of effective controls.

Section 2. The Pathogen Review Committee shall include representatives from FDA, NMFS, EPA; State shellfish control authorities, the shellfish industry, and academia with knowledge of the pathogen(s) or deleterious substances of concern and risk analysis and risk management.

Section 3. The ISSC Executive Board shall set a date for completion of the report to ensure that the ISSC membership is informed. The written committee report shall be presented to the Executive Board or appropriate Task Force for use in its deliberation of the issue.

PROCEDURE XV. PROCEDURE FOR EVALUATION OF SHELLFISH SANITATION PROGRAM ELEMENTS.

Section 1. The goal of shellfish program evaluation shall be to monitor program implementation and work with states to determine where problems may exist and how to address them.

Section 2. Shellfish program evaluation methodologies shall:

Subdivision a. Monitor state program implementation;
Subdivision b. Assess state program effectiveness; and
Subdivision c. Evaluate the validity of the elements of the NSSP Guide for the Control of Molluscan Shellfish.

Section 3. The minimum components of shellfish program evaluation shall include:

Subdivision a. A description of the program activity;
Subdivision b. A comparison of FDA observations with state observations; and
Subdivision c. A measurement of conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish.

Section 4. The focus of data collection shall be on measuring conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish.

Section 5. The types of data collected shall include the following:

Subdivision a. Program records;
Subdivision b. Direct observation made by the evaluator;
Subdivision c. Data and information from the Authority or other pertinent sources.

Section 6. Requirements for evaluation of shellfish sanitation program elements shall include, at a minimum:

Subdivision a. Evaluation of growing area classification;
- Subdivision i. Records audit of sanitary survey;
- Subdivision ii. Bacteriological standards;
- Subdivision iii. Growing area classification;
- Subdivision iv. Marine Biotoxin control;
- Subdivision v. Marinas.

Subdivision b. Evaluation of shellfish plant inspection program;
- Subdivision i. Records audit of past shellfish processing facility inspections;
- Subdivision ii. Direct observation of current shellfish processing facility conditions;
- Subdivision iii. Information collection from the Authority and

other pertinent sources concerning shellfish processing facility inspection program.

Subdivision iv. Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This program element compliance will be based on the following criteria:

Subdivision (a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.

Subdivision (b) 95% of the certified dealers evaluated must have been inspected by the state at the frequency required by the current Guide for the Control of Molluscan Shellfish.

Subdivision (c) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.

Subdivision (d) States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance schedules were not met, that proper administrative action was taken by the State.

Subdivision (e) All critical deficiencies have been addressed by the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.

Subdivision v. Plant Evaluation Criteria

Subdivision (a) Legal Authority – Chapter VIII. @ .01 A. (2) (c). The plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the Dealer

Certification requirements listed in Chapter I @ .01 and @ 02. [Critical]

Subdivision (b) Initial Certification – Chapter I @ 02B. The Plant Sanitation Element will be deemed in compliance with this requirement when all plants are certified in accordance with criteria listed below:

HACCP requirements:

(i) A HACCP plan accepted by the Authority
(ii) No critical deficiencies;
(iii) Not more than 2 key deficiencies;
(iv) Not more than 2 other deficiencies.

Sanitation and additional Model Ordinance Requirements:

(i) No critical deficiencies;
(ii) Not more than 2 key deficiencies;
(iii) Not more than 3 other deficiencies.

Subdivision (c) Inspection frequency – Chapter I @ .02 F. and G. The Plant Sanitation Element will be deemed in compliance with this requirement when no more than one plant inspected doesn't meet the required inspection frequency.

Subdivision (d) Compliance schedules. The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated are found to be without schedules.

Subdivision (e) Follow-Up. The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that they

have performed proper follow-up for compliance schedules for 90% of dealers evaluated and if the compliance schedules were not met that administrative action was taken.

Subdivision (f) Deficiency Follow-up.
The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that all critical deficiencies have been addressed.

Subdivision (g) In-Field Plant Criteria.
The in-field Plant Sanitation Element will be deemed in compliance with this requirement when the plant meets the following criteria:

(i) Shucker/packers and repackers HACCP requirements:
   a. A HACCP plan accepted by the Authority;
   b. No critical deficiencies;
   c. Not more than 4 key deficiencies;
   d. Not more than 4 other deficiencies.

   Sanitation and dditional Model Ordinance Requirements
   a. No critical deficiencies;
   b. Not more than 4 key deficiencies;
   c. Not more than 6 other deficiencies.

(ii) Shellstock shippers and reshippers HACCP requirements:
   a. A HACCP plan accepted by the

authority;
b. No critical deficiencies;
c. Not more than 3 key deficiencies;
d Not more than 3 other deficiencies.

Sanitation and additional Model Ordinance Requirements
a. No critical deficiencies;
b. Not more than 3 key deficiencies;
c. Not more than 5 other deficiencies.

Subdivision vi. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria

Subdivision (a) The overall Plant Sanitation Program element will be assigned one of the following designations:

(i) Conformance: The program is in compliance with all of the criteria listed above.

(ii) Conformance with Deficiencies: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision v. (a), (b), (c), (d), (e), and (f) and has 25% or less of plants with deficiencies associated with key or other compliance items in Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g).

(iii) Non-Conformance: The program is in compliance with Procedure XV. Section 6. Subdivision

(b) Sub-division (v) (a), but, does not meet the criteria in Procedure XV. Section 6. Subdivision (b) Subdivision (v) Sub-division (b) or (c) or (d) or (e) or (f) has greater than 25% (but less than 51%) of plants with deficiencies associated with key or other compliance items Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g).

(iv) Major Non-Conformance: The program has multiple deficiencies. It is non-compliant with Procedure XV. Section 6. Subdivision (b) Subdivision (v) Subdivision (b) or (c) or (d) or (e) or (f) or 51% or greater of plants with deficiencies associated with Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g).

FDA will follow the current compliance program for communication with the State agencies.

Subdivision c. Evaluation of shellfish laboratories;

Subdivision i. Records audit of laboratory operations;

Subdivision ii. Direct observation of current laboratory operating conditions;

Subdivision iii. Information collection from the Authority and other pertinent sources concerning laboratory operations.

Subdivision d. Evaluation of shellfish growing area patrol;

Subdivision i. Records audit of past patrol activities;

Subdivision ii. Direct observation of current patrol activities;

Subdivision iii. Information collection from the Authority and other pertinent sources.

PROCEDURE XVI. PROCEDURE FOR THE APPROVAL OF ANALYTICAL METHODS FOR THE NSSP

Section 1. Prior to NSSP adoption, all laboratory methods shall be evaluated by the ISSC. Persons interested in submitting a method for inclusion in the NSSP must submit a pre-proposal outlining the following:

a. Description of Method;
b. Proposed Use of Method; and
c. Time Table for SLV

Section 2. The submitter of the proposal will be notified by the ISSC Executive Office of the action taken on the pre-proposal by the ISSC.

Section 3. Submitters of pre-proposals receiving approval will be requested to submit a full proposal to the ISSC and a liaison from the Laboratory Methods Review Committee will be assigned.

Section 4. The full proposal shall be submitted to the ISSC in proposal form requesting approval of the analytical method for use in the NSSP.

Subdivision a. All proposals shall include a completed Single Laboratory Validation (SLV) Method Application and Checklist. AOAC approved methods that have undergone the AOAC Official Methods of Analysis (OMA) or FDA Office of Foods Level 3 or 4 validations may be accepted as an NSSP method without Single Lab Validation providing the AOAC or FDA multi-laboratory validation was performed in the raw molluscan shellfish matrix for which the Conference intends it to be used and is deemed by ISSC as fit for purpose. Submitters of AOAC and FDA validated methods will provide a Single Laboratory Validation Method Application and Checklist along with the AOAC OMA or FDA Office of Foods Level 3 or 4 validations.

Subdivision b. The ISSC Executive Director shall submit the proposal to the Laboratory Methods Review Committee for review and development of recommendations to Task Force I.

Section 5. Within six (6) months of receipt the Laboratory Methods Review and Committee will review the proposal package for completeness and recommend to the Executive Board the suitability of the method for a full review for possible inclusion into the NSSP. The recommendation of the Executive Board will be presented to the ISSC Voting Delegates for approval.

Section 6. Review by Laboratory Methods Review Committee;

Subdivision a. Within six (6) months of receipt of a complete application proposal, the Laboratory Methods Review Committee shall conduct an

evaluation of the data which describes the performance characteristics of the new proposal, the AOAC approved method or FDA Office of Foods Level 3 or 4 method;

Subdivision i. These performance characteristics include:

- Subdivision (a) Accuracy (Trueness);
- Subdivision (b) Measurement uncertainty;
- Subdivision (c) Precision;
- Subdivision (d) Recovery;
- Subdivision (e) Specificity;
- Subdivision (f) Linear range;
- Subdivision (g) Limit of detection;
- Subdivision (h) Limit of quantitation (sensitivity);
- Subdivision (i) Ruggedness;
- Subdivision (j) Comparability if applicable (comparison of the performance of the new/modified method to the accepted method.

Subdivision ii. Method documentation including:

- Subdivision (a) Method title, scope and references;
- Subdivision (b) Equipment and reagents required;
- Subdivision (c) Sample collection, preservation and storage requirements;
- Subdivision (d) Safety requirements;
- Subdivision (e) Step by step procedure;
- Subdivision (f) Specific quality control measures associated with the method;
- Subdivision (g) Cost of the method;
- Subdivision (h) Sample turnaround time.

Subdivision iii. Specific application(s);

Subdivision b. Review of need for the method;

- Subdivision i. Method meets an immediate or continuing need;
- Subdivision ii. Improves analytical capability under the NSSP as an alternative to an accepted method(s);
- Subdivision iii Replaces other approved or accepted method(s).

.

Section 7. The Laboratory Methods Review Committee shall submit one of the following recommendations to Task Force I within six (6) months of receiving a complete proposal application for a method:

Subdivision a. Non-acceptance pending further information as defined by the Committee;

Subdivision b. Accept as an Approved NSSP Method;
Subdivision c. Accept as an Approved Limited Use NSSP Method;
Subdivision d. Accept as an Emergency Use NSSP Method.

Section 8. Requests for ISSC recantation of an approved method shall be submitted using the ISSC proposal form. The request for recantation must include reason for the request, i.e. the need no longer exists, poor performance, equipment or reagents no longer available, etc.

Section 9. Types of NSSP Analytical Methods.

Subdivision a. Approved NSSP Methods.

Approved NSSP methods are those accepted for use as permanent methods and cited in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. These methods have been long used in the NSSP or have completed the Single Laboratory Validation Method Protocol to show that the method is fit for purpose in the NSSP. Approved NSSP Methods have been:

Subdivision i Described in a scientific or other peer-reviewed professional publication;
Subdivision ii. Used successfully to detect or quantify;
Subdivision iii. Evaluated and the performance characteristics for specific applications have been determined and found fit for purpose;
Subdivision iv. Collaboratively studied and/or collaboratively tested.

Subdivision b. Approved Limited Use Methods.

Approved Limited Use Methods are methods accepted for use in NSSP and listed in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. These methods are alternative methods within the NSSP that can meet an immediate need of the NSSP, improve turnaround time, cost effectiveness, and/or increase analytical capacity. Approved Limited Use Methods can include screening, provisional, or methods with limitations as defined by the LMRC evaluation of the method.

Subdivision c. Emergency Use Methods.

Emergency Use Methods are methods used to meet an immediate or ongoing critical need for a method of analysis and no NSSP approved method exists. Emergency Use Methods may be given interim approval by the ISSC Executive Board provided the following criteria are provided:

Subdivision i. Name of Method;

Subdivision ii. Date of Submission;
Subdivision iii. Specific purpose or intent of the method for use in the NSSP;
Subdivision iv. Step-by-step procedure including equipment, reagents and safety requirements necessary to run the method;
Subdivision v. Data generated in support of the efficacy of the method if available;
Subdivision vi. Any peer reviewed articles detailing the method and its efficacy;
Subdivision vii. Name of the developer or SSCA submitter; and
Subdivision viii. Developer or submitter contact information.

PROCEDURE XVII. PROCEDURE FOR *Vibrio vulnificus (V.v.)* ILLNESS REVIEW COMMITTEE PROCEDURES

Section 1. Committee Charge

The *V.v.* Illness Review Committee will annually review all *V.v.* cases involving the consumption of shellfish which are reported to FDA regional specialists and the Center for Disease Control (CDC). The Committee will determine which cases meet the case definition of a National Shellfish Sanitation Program (NSSP) *V.v.* case as outlined in Model Ordinance Section II. Chapter II. @.05. All cases meeting the NSSP definition will be included in an annual report which will be presented to the Interstate Shellfish Sanitation Conference (ISSC) Executive Board and the Vibrio Management Committee. Following ISSC Executive Board approval the report will be made available to the ISSC membership and posted on the ISSC website. This data is expected to be used by USFDA, State Authorities, and the ISSC for the following purposes:

Subdivision a. Conducting annual *V.v.* Risk Evaluations;
Subdivision b. Risk per serving determinations;
Subdivision c. *V.v.* Control Plan Evaluations;
Subdivision d. *V.v.* Contingency Plan Evaluations; and
Subdivision e. Reviewing illness trends.

Section 2. Procedures.

Subdivision a. The Committee will only consider cases that are reported on a CDC and Prevention Cholera Vibrio Illness Surveillance Report (COVIS) Form CDC 52.79 or other means.
Subdivision b. FDA will coordinate the collection of cases and COVIS forms, and other information and after redacting identifying information will make this information available to the Committee.
Subdivision c. The information from the COVIS forms will be shared with the *V.v.* Illness Review Committee for review.

Subdivision d. The *V.v.* Illness Review Committee will review the cases and incorporate the appropriate information into a chart which will serve as the Committee report.

Subdivision e. The report will be presented to the ISSC Executive Board for approval and then forwarded to the Vibrio Management Committee.

Subdivision f. The availability of the report will be announced to the ISSC membership.

A copy of the report will be posted on the ISSC website.

Section 3. Criteria and Guidelines.

The Committee will use the following criteria and guidelines in reviewing reported cases:

Subdivision a. Was the illness etiologically confirmed? In thiscontext "etiologically confirmed "shall mean laboratory confirmation by wound, stool or blood culture. Confirmation may be by a laboratory otherthan a State laboratory."

Subdivision b. Was the illness epidemiologically linked to shellfish? Epidemiologically linked will mean"associated with" the consumption of oysters. Consumption means ingested; eaten within 7 days of onset of symptoms. Date of onset may be before hospitalization. Further information may be warranted; discretion may be exercised.

Subdivision c. Were the shellfish commercially harvested? Commercially harvested shall mean the shellfish were intended for sale or distribution in commerce. Commercial harvest will include those cases involving a foreign state.

Subdivision d. Were the shellfish raw or undercooked? If the victim developed *V.v.* septicemia after consumption the shellfish are considered to have been raw or undercooked.

Subdivision e. From what State was the shellfish harvested?

Subdivision f. Did the case involve septicemia from consumption:

The following guidance will be used in determining if the case is a septicemia or a gastroenteritis case. Clinical signs and symptoms *V.v.* septicemia include:

Subdivision i. *V.v.* bacteria isolated from blood.

Subdivision ii. Fever measured as above 100 degree Fahrenheit.

Subdivision iii. Death as outcome (septicemia has a mortality rate of over 50% - 70%).

Subdivision iv. Bullae (blood filled blisters) but this also can occur after a wound infection which becomes septic.

Subdivision v. Shock because of the sepsis (again this can happen also because of a wound infection).

Subdivision g. Indications case may not be *V.v.* septicemia from consumption:

Subdivision i. Bacteria are only isolated from wound fluid or stool and no clinical evidence of septicemia.

Subdivision ii. Cellulitis. Since cellulitis is a localized or diffuse inflammation of connective tissue with severe inflammation of dermal and subcutaneous layers of the skin (bacteria entering bodies through the skin, there might be a visible wound or just a small scratch), therefore more likely a wound infection.

Subdivision iii. History of pre-existing and sustained wound infection (If both wound and oyster/seafood consumption is documented and happened within the incubation period, there is no way to differentiate why the patient is septic.)

Subdivision iv. Septicemia has a much shorter incubation period compared to gastroenteritis, according to CDC data. *V.v.* septicemia has an incubation period between 12-72 hours, although we have seen cases with shorter incubation periods.

Section 4. Challenges to Committee Findings.

Persons wishing to challenge the information included in the report must notify the ISSC Executive Director within sixty (60) days of the posting of the report on the ISSC website. The ISSC Executive Board will review all challenges at the next scheduled Executive Board meeting.

ISSC *Vibrio vulnificus* Illness Review Criteria Table

Review Date: _____

Case Identifier/Number:	**Criteria Status Determination**		
Criteria	**Yes**	**No**	**Unknown**
1. Etiologically Confirmed Blood Stool			
2. Epidemiologically Linked?			
3. Septicemia Illness?			
4. Reporting State?			
5. Commercial Harvest?			
6. Were shellfish consumed?			
a. Specify shellfish consumed:	**Oysters**	**Clams**	**Specify Other**
b. Date of consumption: _____			
c. Is onset consistent with consumption of shellfish? Date of onset _____			
7. Trace-back Information			
a. Were shipping tags available? If other trace-back information reported, list:			
b. State of harvest, harvest area (s), and harvest date (list all reported).			

Harvest Area	Harvest State	Harvest Date	Species	Comment

ISSC *V.v.* Illness Review Form (06/28/2013)

PROCEDURE XVIII. RECIPROCITY

Reciprocity for the purpose of ISSC agreements shall mean that no action or requirements on the part of any regulatory authority will cause or require any action in excess of the requirements of the NSSP or the ISSC agreements. The intent of this procedure is to ensure that state actions do not unnecessarily restrict interstate shipment of shellfish conforming to the reciprocity of the NSSP. The ISSC recognizes that States should be allowed to appropriately respond to public health emergencies that could restrict interstate shipment of shellfish. Procedure XVIII. Section 1. Notification and Consultation provides adequate opportunity for communication between interested parties that could include State and Federal regulatory agencies and the industry.

Section 1. Notification and Consultation.

A State, prior to taking an action that may fail to meet the definition of "reciprocity," must first notify and consult with the Executive Board. Notification should be as far in advance as is reasonably possible in order to take into account the views of the ISSC prior to a decision to take the action. The State should provide the rationale for the proposed action by describing, at a minimum:

- The potential effect on the public health within that State;
- The potential effect on the public health in other States;
- The potential economic impact on States;
- The necessity for the action within the proposed timeframe; and
- How the proposed actions are consistent with Procedure I. requirements relating to uniformity and the importance of operating within a collective framework.

A State may also notify the ISSC Executive Board upon learning of another State's intention to take action that may violate Procedure V.

Section 2. Consideration.

If, after fully considering the State's rationale for the proposed actions, the Executive Board determines that the State's actions are unwarranted and contrary to the interests of the collective membership, the Executive Board shall so advise the State. If the State takes the proposed action after being so advised, or fails to follow Procedure V., the Executive Board will commence a formal Procedure V. process.

Section 3. Formal Procedure V. Process.

The process will include written notification to all States involved (initiating and affected States), to present findings on the scientific and public health issues raised, which support their respective views or actions on the issue, along with identification of the formal procedural process and timeline.

All affected States (initiating and affected States), shall present the following information to the ISSC Executive Board:

- Scientific and related public health issues.

- Economic issues.
- Other relevant issues.
- Rationale why Procedure V. has/has not been violated.
- Alternate Actions for consideration.

The Executive Board determination will include Findings of Facts and Conclusions.

Section 4. Censure.
If the State takes the proposed action after being so advised, or fails to follow Procedure V., the Executive Board may place the State under censure until such time as removed from the censure by the Executive Board and so inform the Governor of that State in writing. A State under censure may attend all functions and otherwise exercise rights as a member of the ISSC, but may not vote, either in committees, task forces, or in the General Assembly. The Executive Board reserves the right to take additional actions against the non-compliant State.

PROCEDURE XIX. EXECUTIVE BOARD PROCEDURES FOR ESTABLISHING MEMBERSHIP FEES

Section 1. The ISSC Executive Board will follow these guidelines in establishing membership fees for State and individual members.

Subdivision a. Membership fees will be established as necessary to provide at a minimum ten percent (10%) of the operating costs of the ISSC.

Subdivision b. The Executive Board will consider appropriate changes to the minimum of ten percent (10%) should decreases in other funding sources occur.

Subdivision c. The Executive Board will allocate travel assistance to member States when the revenue acquired from membership fees is not critical to support the Conference operating budget.

Interstate Shellfish Sanitation Conference
2014-2015 Executive Board

CHAIRMAN
Maryanne Guichard – Term Expires 2015
Washington Department of Health
P.O. Box 47824
Olympia, WA 98504
Phone: (360) 236-3391
Fax: (360) 236-2257
Email: maryanne.guichard@doh.wa.gov

VICE CHAIR (Non-Voting)
Patti Fowler – Term Expires 2015
NC Department of Environment & Natural Resources
5285 Highway 70 West
Morehead City, NC 28557
Phone: (252) 808-8147
Fax: (252) 726-8475
Email: patti.fowler@ncdenr.gov

ISSC EXECUTIVE DIRECTOR (Non-Voting)
Ken B. Moore
Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223
Phone: (803) 788-7559
Fax: (803) 788-7576
Email: issc@issc.org

OFFICE MANAGER and PROGRAM CHAIR (Non-Voting)
William Eisele
280 Old Tuckahoe Road
Petersburg, NJ 08270
Phone: (609) 628-2758
Fax: (609) 628-3220
Email: beisele@comcast.net

REGION 1 REGULATORY
Mike Hickey – Term Expires 2015
MA Fisheries and Wildlife
1213 Purchase Street
New Bedford, MA 02740
Phone: (508) 990-2860
Fax: (508) 990-0449
Email: michael.hickey@state.ma.us
Alternate: Eric M. Hickey

REGION 1 INDUSTRY
Lori Howell – Term Expires 2017
Spinney Creek Shellfish, Inc.
P.O. Box 310
Eliot, ME 03903
Phone: (207) 439-2719
Fax: (207) 439-7643
Email: lahowell@spinneycreek.com
Alternate: Bob Rheault

REGION 2 REGULATORY
Dave Carey – Term Expires 2017
CT Department of Agriculture
190 Rogers Avenue
Millford, CT 06460
Phone: (203) 874-0696
Fax: (203) 783-9976
Email: davecarey@ct.gov
Alternate: Bruce Friedman

REGION 2 INDUSTRY
Steve Fleetwood – Term Expires 2015
Bivalve Packing Company
P.O. Box 336
Port Norris, NJ 08349
Phone: (856) 785-0270
Fax: (856) 785-1406
Email: eastpointoysters@aol.com
Alternate: Jimmy Bloom

REGION 3 REGULATORY
Julie Henderson – Term Expires 2015
VA Department of Health
109 Governor Street, Suite 614B
Richmond, VA 23219
Phone: (804) 382-3223
Fax: (804) 864-7481
Email: julie.henderson@vdh.virginia.gov
Alternate: Kathy Brohawn

REGION 3 INDUSTRY
A.J. Erskine – Term Expires 2017
Bevans Oyster Co.
1090 Skipjack Road
Kinsale, VA 22488
Phone: (804) 472-2331
Fax: (804) 472-4575
Email: ajerskine@bevansoyster.com
Alternate: Pete Jensen

Interstate Shellfish Sanitation Conference
2014-2015 Executive Board

REGION 4 REGULATORY
Patti Fowler – Term Expires 2017
NC Department of Environment & Natural Resources
5285 Highway 70 West
Morehead City, NC 28557
Phone: (252) 808-8147
Fax: (252) 726-8475
Email: patti.fowler@ncdenr.gov
Alternate: Steve Murphey

REGION 4 INDUSTRY
Tommy Ward – Term Expires 2015
Buddy Ward & Son's Seafood & Trucking LLC
P.O. Box 698
Apalachicola, FL 32329
Phone: (850) 653-8522
Fax: (850) 653-9845
Email: buddywardtrking@yahoo.com
Alternate: Robert Webb

REGION 5 REGULATORY
Joe Jewell – Term Expires 2015
Mississippi Department of Marine Resources
1141 Bayview Avenue
Biloxi, MS 39530
Phone: (228) 374-5000
Fax: (228) 374-5220
Email: joe.jewell@dmr.ms.gov
Alternate: Vacant

REGION 5 INDUSTRY
Chris Nelson - Term Expires 2017
Bon Secour Fisheries Inc.
PO Box 60
Bon Secour, AL 36511
Phone: (251) 949-7411
Fax: (251) 949-3478
Email: cnelson@bonsecourfisheries.com
Alternate: Tracy Woody

REGION 6 REGULATORY
Jerrod Davis – Term Expires 2017
WA Department of Health
P.O. Box 47824
Olympia, WA 98504
Phone: (360) 236-3330
Fax: (360) 236-2257
Email: jerrod.davis@doh.wa.gov
Alternate: Kim Stryker

REGION 6 INDUSTRY
Margaret Barrette – Term Expires 2015
Pacific Coast Shellfish Growers Association
120 State Avenue NE #142
Olympia, WA 98501
Phone: (360) 754-2744
Fax: (360) 754-2743
Email: margaretbarrette@pcsga.org
Alternate: Bill Dewey

NON-PRODUCING STATE
Quincy Boyce – Term Expires 2017
UT Department of Agriculture & Food
350 North Redwood Road
Salt Lake City, UT 84114 USA
Phone: (801) 538-7144
Fax: (801) 538-4949
Email: wboyce@utah.gov

NON-PRODUCING STATE
Terri Gerhardt – Term Expires 2017
Ohio Department of Agriculture
8995 East Main Street
Reynoldsburg, OH 43068
Phone: (614) 728-6250
Fax: (614) 644-0720
Email: gerhardt@agri.oh.gov

NON-PRODUCING STATE
Bruce Flippens – Term Expires 2015
District of Columbia Department of Health
899 North Capitol Street NE
Washington, DC 20002
Phone: (202) 724-8800
Fax: (202) 724-8677
Email: bruce.flippens@dc.gov

NON-PRODUCING STATE ALTERNATE 1:
Johnathan Gerhardt, NM
NON-PRODUCING STATE ALTERNATE 2:
Clark Wilson, CO
NON-PRODUCING STATE ALTERNATE 3:
Tim Anderson, WI

NMFS REPRESENTATIVE
Calvin Walker
National Marine Fisheries Service
705 Convent Street
Pascagoula, MS 39568
Phone: (228) 769-8964
Fax: (228) 762-7144
Email: calvin.walker@noaa.gov

Interstate Shellfish Sanitation Conference
2014-2015 Executive Board

US FDA REPRESENTATIVE
Paul DiStefano, Office of Seafood
U.S. Food and Drug Administration, CFSAN
5100 Paint Branch Parkway
College Park, MD 20740
Phone: (301) 436-1410
Fax: (301) 436-2601
Email: paul.distefano@fda.hhs.gov

EPA REPRESENTATIVE (Non-Voting)
Bill Kramer U.S. EPA
1200 Pennsylvania Ave. NW Rm 6210-TT,
Mail Code 4305T
Washington DC 20460
Phone: (202) 566-0385
Fax: (202) 566-0409
Email: kramer.bill@epamail.epa.gov

AFDO REPRESENTATIVE (Non-Voting)
Julie Henderson
VA Department of Health
109 Governor Street, Suite 614B
Richmond, VA 23219
Phone: (804) 382-3223
Fax: (804) 864-7481
Email: julie.henderson@vdh.virginia.gov

NW INDIAN FISHERIES COMM (Non-Voting)
David Fyfe, Tribes Advisor
Northwest Indian Fisheries Commission
Post Office Box 498
Suquamish, WA 98392
Phone: (360) 598-6077
Fax: (360) 598-6110
Email: dfyfe@nwifc.org

PATROL ADVISOR (Non-Voting)
Mike Pearson
SC Department of Health & Environmental Control
927 Shine Ave
Myrtle Beach, SC 29577
Phone: (843) 238-4378
Fax: (843) 238-4518
Email: pearsodm@dhec.sc.gov

CONSUMER ADVISORY REPRESENTATIVE (Non-Voting)

VACANT

RETAIL ADVISORY REPRESENTATIVE (Non-Voting)

VACANT

CONFERENCE FOR FOOD PROTECTION (Non-Voting)
Gregory A. Pallaske, Director of Regulatory Compliance
U.S. Food Service Food Safety & Quality Assurance
U.S. Foodservice
Phone: (847) 232-5884
Cell: (312) 259-8859
Fax: (847) 232-5049
Email: Greg.Pallaske@USFood.com

PAST CHAIRMAN (Non-Voting)
Keith Skiles
Virginia Department of Health
109 Governor Street 6th Floor
Richmond, VA 23219
Phone: (804) 864-7479
Fax: (804) 864-7481
Email: keith.skiles@vdh.virginia.gov

VIBRIO MANAGEMENT COMMITTEE CHAIR (Non-Voting)
Keith Skiles
Virginia Department of Health
109 Governor Street 6th Floor
Richmond, VA 23219
Phone: (804) 864-7479
Fax: (804) 864-7481
Email: keith.skiles@vdh.virginia.gov

TASK FORCE I CHAIR (Non-Voting)
Patti Fowler
NC Department of Environment & Natural Resources
5285 Highway 70 West
Morehead City, NC 28557
Phone: (252) 808-8147
Fax: (252) 726-8475
Email: patti.fowler@ncdenr.gov

TASK FORCE II CHAIR (Non-Voting)
Lori Howell
Spinney Creek Shellfish, Inc.
P.O. Box 310
Eliot, ME 03903
Phone: (207) 439-2719
Fax: (207) 439-7643
Email: lahowell@spinneycreek.com

TASK FORCE III CHAIR (Non-Voting)
Kirk Wiles
Texas Dept of State Health Services
P.O. Box 149347
Austin, TX 78714
Phone: (512) 834-6757
Fax: (512) 834-6762
Email: kirk.wiles@dshs.state.tx.us

Region 1 - Maine, New Hampshire, Massachusetts, Rhode Island
Region 2 - Connecticut, New York, New Jersey
Region 3 - Maryland, Delaware, Virginia
Region 4 - North Carolina, South Carolina, Georgia, Florida
Region 5 - Alabama, Mississippi, Louisiana, Texas
Region 6 - Alaska, Washington, Oregon, California, Hawaii
Non-Producing States - All Inland States

ISSC

A G E N D A

Page

I. CALL TO ORDER

II. ROLL CALL

III. EXECUTIVE BOARD VACANCIES

A. Consumer Advisory Representative
B. Retail Advisor Representative
C. Conference for Food Protection Representative

IV. MINUTES

V. INTRODUCTORY COMMENTS

A. Chairman Maryanne Guichard
B. FDA Paul DiStefano
C. NMFS Calvin Walker and Jon Bell
D. EPA Joel Hansel for Bill Kramer

VI. PROGRAM CHAIRMAN'S REPORT

A. 2015 Spring Board Meeting
B. 2015 Biennial Meeting
C. Format for Biennial Meeting

VII. COMMITTEE REPORTS

A. Executive Committee

3. FDA Small Conference Grant Final Report (due 10/31/2014)

C. Recall Guidance Committee Report and Recommendations
D. Laboratory Methods Review Committee
1. *V.p.* Methods

VIII. OLD BUSINESS

C. 2013 NSSP Guide for the Control of Molluscan Shellfish
D. US/EU Shellfish Agreement

I. CALL TO ORDER

Chairman Keith Skiles called the meeting to order at 1:35 PM on May 27, 2014.

II. THE PASSING OF THE GAVEL

Keith Skiles thanked the Board for their support during his term and then passed the gavel to Maryanne Guichard, Chair Elect.

III. ROLL CALL

Ken Moore conducted roll call. The following members were present:

Board Members Present:	Representing:
Maryanne Guichard	Chair
Keith Skiles	Past Chair / VMC Chair
Patti Fowler	Vice Chair / Region 4 Regulatory / Task Force I Chair
Ken Moore	ISSC Executive Director
William Eisele	Program Chair / Conference Office Manager
Mike Hickey	Region 1 Regulatory
Lori Howell	Region 1 Industry / Task Force II Chair
Dave Carey	Region 2 Regulatory
Steve Fleetwood	Region 2 Industry
Julie Henderson	Region 3 Regulatory / AFDO Representative
Tommy Ward	Region 4 Industry
Jerrod Davis	Region 6 Regulatory
Margaret Barrette	Region 6 Industry
Terri Gerhardt	Non-Producing State
Quincy Boyce	Non-Producing State
Bruce Flippens	Non-Producing State
Paul DiStefano	FDA
Calvin Walker	NOAA
Bill Kramer	EPA
David Fyfe	Northwest Indian Fisheries Commission
Kirk Wiles	Task Force III Chair

Board Members Absent:	
A.J. Erskine	Region 3 Industry
Joe Jewell	Region 5 Regulatory
Chris Nelson	Region 5 Industry
Mike Pearson	Patrol Advisor
Greg Pallaske	Conference for Food Protection Representative

ISSC staff was also present.

IV. MINUTES

Maryanne Guichard advised Board members that a copy of the draft minutes for the March 6-7, 2013, January 27, 2014, and January 31, 2014, meetings had been provided in the Board materials. In response to an inquiry by Margaret Barrette, Ken Moore advised the Board that the Executive Office will re-distribute the Conflict of Interest Statement to Board members and ask for any comments within thirty (30) days of distribution. Paul DiStefano asked that his introductory comments in the January 31, 2014, minutes be corrected to state that the EU and FDA are working to recognize Spain, the Netherlands and the UK for US shipment and nothing is being

shipped at this time. Following comments on editorial corrections which will be made by the Executive Office, a motion (Lori Howell) was made that the minutes be approved. A second (Bruce Flippens) was made and the motion carried with a voice vote by the Board.

V. INTRODUCTORY COMMENTS

A. ISSC EXECUTIVE BOARD CHAIRPERSON

Maryanne Guichard said she is honored to be the new Chair and expressed her appreciation to Keith Skiles for his service as Chairman.

B. FDA

Paul DiStefano provided the following information to the Board:

1. Thanked Keith Skiles for his service as Chairman;
2. Bill Watkins will be retiring this year; and
3. The China ban on west coast product has been lifted.

C. NOAA

Calvin Walker provided the following updates to the Board:

1. Geoff Scott (Charleston Lab) will be leaving NOAA on June 1st to assume Chairmanship of the Department of Environmental Health Sciences at the University of SC in Columbia;
2. The suspension of receiving geoduck in China had been lifted; and
3. NOAA will be providing support for Vibrio research and forecasting models at the Seattle Research Center.

D. EPA

Bill Kramer did not have any additional comments since the last Board meeting.

V. PROGRAM CHAIRMAN'S REPORT

A. 2015 Meeting

Bill Eisele reported that the 2015 Biennial Meeting would be held in a non-producing State. He said Cleveland or Cincinnati, Ohio; Nashville or Memphis, Tennessee; and Salt Lake City, Utah would be considered. He will provide a follow-up at the October 2014 Board meeting.

B. Executive Board Meeting Schedule

Bill Eisele reported that the next Executive Board meeting would be held either October 6 & 7 or October 14 & 15 in Atlanta or Charlotte. Ken Moore asked Board members to send an email to the ISSC Executive Office stating their preference.

VI. EXECUTIVE COMMITTEE REPORT

A. Executive Committee

Ken Moore updated the Board on the following items:

1. Our FDA Cooperative Agreement will end August 31st. FDA has advised that our 2015 funding should be available September 1st.
2. The FDA Small Conference Grant will be closed out as soon as the remaining paperwork is received for the final two travel expense reimbursements.
3. The 2014 draft budget was shared with the Board in San Antonio but due to time constraints approval was carried over to this meeting. Minor adjustments have been made to accommodate the permanent status of Cathy Mantooth. A motion (Lori Howell) was made and seconded (Mike Hickey) to approve the budget as submitted. The motion passed with a voice vote by the Board.

VII. OLD BUSINESS

NOTE: Paul DiStefano asked for an update on the status of posting the State Vibrio Plans on the ISSC website. Ken Moore will check on this and report back to the Board.

A. 2013 Work Plan Evaluation
B. 2014 Work Plan Approval

Maryanne Guichard asked Board members to provide any comments on the 2013 Work Plan Evaluation and/or the 2014 Work Plan Draft to the Executive Office within the next (30) days.

C. *V.v.* Illness Review Committee Database

Ken Moore reported that the Committee had held a conference call and discussed the development of a database. He said there have been discussions with FDA on who will assume responsibility for the data base when Marc Glatzer retires. Ken said it has not been determined what type of database is needed to be able to look at fields and sort the data. Lori Howell said the Committee is moving forward and there are no current cases that need review.

D. Harvester and Dealer Training Programs
E. MSC Informational Meeting

Ken Moore informed Board members that the Executive Office has received notification of contract approval from NoreCORE for the award of monies which included funding for the harvester and dealer training programs and the MSC Informational Meeting.

Ken also reported that the MSC Oversight Committee had a conference call on Thursday to discuss the MSC Informational Meeting. He said that FDA will be providing travel expense support to the meeting attendees and NoreCORE will be providing funding for other activities and reviewing data. Ken said Geoff Scott is now with the University of SC School of Public Health and has offered the services of a graduate student to help with the MSC data call, project activities and project review.

F. FDA State Evaluations

Julie Henderson asked for a follow-up on the status of a report from FDA which was requested at the January 31, 2014, Board meeting. The request was that FDA report their compliance schedule and whether or not the frequency of that schedule is being met by FDA. Ken Moore said a report had been received from FDA and due to time limits this item was not on the agenda for today's conference call meeting. Paul DiStefano asked that Julie furnish written clarification of this request.

VIII. NEW BUSINESS

A. FDA Response to 2013 Summary of Actions

Ken Moore said that items needing Board action had been identified and reported the following:

1. Proposal 13-200 Reducing the risk of Vibrio illnesses

FDA concurred with ISSC referral of Proposal 13-200 to Committee. As appropriate, FDA will provide support to the Committee via participation of Agency *Vibrio* research and risk assessment experts to assist in addressing Committee charges as set forth in Proposal 13-200. The Agency will look to the Conference to advance recommendations made by the Committee for purposes of implementing appropriate controls to reduce the *Vibrio* risk. Results of ISSC actions in response to Proposal 13-204 will be integral to answering key questions associated with the Committee's charges.

2. Proposal 13-202 Requirements for Outbreaks of Shellfish Related Illnesses
    - A national conference call was held to discuss Vibrio illness reporting.
    - ISSC and FDA will coordinate and prepare for a national conference call with State Shellfish Control Authorities to talk about 2014 implementation of 13-202.

Proposal 13-202 was adopted without a specific implementation date. Given its significance and intended public health benefits, FDA recommends Conference action to establish immediate implementation.

- Recommended establishing an official implementation date of June 1, 2014. A motion was made and seconded that the Board approve the implementation date of June 1, 2014. The motion carried with a voice vote by the Board.
- Recommended remaining issues are included in VMC charge for discussion.

Attribution of cases to a state and harvest area:
- How will multi-source illnesses be handled?
- What are the public health rationale and criteria for case exclusion?

1/100,000 risk per serving:
- What is the process/criteria for determining risk/serving and compliance?

How can retrospective annual risk/serving determinations be used to evaluate performance of state V.p. control plans?
- Illness reporting:
- Timeliness of reporting to state shellfish authorities
- Engaging state epidemiologists and local health agencies to improve reporting of State notification of illnesses to ISSC and FDA

Performance criteria for evaluating state compliance

A motion to adopt this recommendation was made and seconded. The motion carried with a voice vote by the Board.

3. Proposal 13-203 Annual Assessment of Shellfish Production & Utilization

Although not required by Proposal 13-203 as adopted, reporting landings by product category (half shell, post-harvest processing, shucked, etc.) would enable greater refinement to risk per serving calculations associated with shellfish intended for the half shell market.

- Recommended the Executive Office communicate with States asking, when available, to provide this information. A motion was made and seconded to approve the recommendation. The motion carried with a voice vote by the Board.

4. Proposal 13-204 Vibrio Control Plans

FDA has secured initial funds in the amount of $75,000 for the ISSC to begin implementation of Proposal 13-204. These funds will serve to assist States with

studies that support the intent of the substitute proposal. FDA is also looking at ways to provide resources and expertise from its Gulf Coast Seafood Laboratory to assist States with additional studies.

- Recommended appointing a committee to identify the type of studies that support the intent of 13-204 and the criteria for that should be used by ISSC in awarding funding. A motion was made and seconded to approve the recommendation. The motion carried with a voice vote by the Board.

5. Proposal 13-205 V.v. Control Plan Evaluations
   FDA continues to encourage States required to implement a *V.p.* or *V.v.* Control Plan to develop analytical capability and capacity to monitor total and pathogenic Vibrio levels. States are further encouraged to link Vibrio levels to corresponding environmental data, including air temperature, water temperature and salinity.
   - No Recommendation for action by the Board.

6. Proposal 13-206 Analytical Capability & Capacity for Vibrio Testing
   Most shellfish producing States experience environmental conditions within their shellfish growing areas at certain times that present a greater Vibrio risk. Development of the analytical capability and capacity to test for Vibrio within each state will greatly facilitate the characterization and control of this risk with regard to season, location, environmental conditions and industry practices. While Proposal 13-206 was not adopted by the Conference, FDA continues to encourage States required to implement a V.p. or V.v. Control Plan to develop analytical capability and capacity to monitor total and pathogenic Vibrio levels. States are further encouraged to link Vibrio levels to corresponding environmental data, including air temperature, water temperature and salinity. This will help establish baseline data that can be used to assess the effectiveness of Vibrio Control Plans and to make Vibrio management and control decisions. FDA has assisted a number of States with enhancing their Vibrio analytical capability and capacity by providing guidance, training and performance assessment. It is the intent of the Agency to continue to make this assistance available to ISSC stakeholders.
   - Recommended the Executive Office communicate with States to encourage them to gather this data where they can. A motion was made and seconded to approve the recommendation. The motion carried with a voice vote by the Board.

7. Proposal 13-209 Re-submerging of Shellstock
   FDA concurs with Conference action to refer Proposal 13-209 to committee. Proposal 13- 209 requires that a study be conducted to ensure that shellstock transplanted or re-submerged, for purposes of mitigating levels of naturally occurring pathogens, are allowed sufficient time to reduce levels to background. While the intended purpose of re-submerging is to reduce naturally occurring pathogens such as Vibrio spp. to pre-harvest levels, re-submerging also has the potential to greatly increase Vibrio levels, especially if shellstock purging is limited as a result of environmental conditions, handling practices, over-stacking, etc. If shellstock cannot effectively pump, Vibrio levels will remain the same or possibly increase, depending on water temperature. While re-submerging can effectively reduce Vibrio levels, as demonstrated by FDA-ISSC studies conducted in 2013, effective application needs to be scientifically demonstrated.

- Recommended Executive Office advise States this proposal was sent to Committee but ISSC suggests if a State is going to allow resubmerging that the State be careful to consider that the possibilities of resubmerging in certain ways will increase risk and ask States to give thought to this when permitting such activities. A motion was made and seconded to approve the recommendation. The motion carried with a voice vote by the Board.

B. V.p. Illnesses Data Conference Call (April 23, 2014)
Ken Moore reported ISSC and CDC held a national conference call to present data on Vibrio illness reporting. He said ISSC had received positive feedback from CDC.

C. 2013 NSSP Guide for the Control of Molluscan Shellfish
Ken Moore advised the Board that the process to update the Guide would begin since the Board has taken action on FDA's Response to the Summary of Actions.

D. 2014-2015 Committee Charges and Rosters
Following a discussion a motion was made and seconded to approve the rosters and charges for the 2014-2015 committees listed below with the following changes:

- Add Communications Committee
- Add Lori Howell to the Shellfish Resubmerging Committee
- Change Angela Ruple to NOAA on the Growing Area Classification Committee

1. Aquaculture Facility Inspection
2. Biotoxin
3. Chemical Contamination
4. Education
5. Foreign Relations
6. Growing Area Classification
7. HACCP Review
8. Import Assessment
9. Laboratory Methods Review & Quality Assurance
10. MSC Committee
11. Model Ordinance Effectiveness
12. NSSP Evaluation Criteria
13. Pathogen Review
14. Patrol
15. Plant Standardization Advisory
16. Post-Harvesting Processing
17. Program Review
18. Proposal Review
19. Recall Guidance
20. Research Guidance
21. Resolutions
22. Shellfish Restoration
23. Time/Temperature
24. Traceability
25. Use of Press
26. Vibrio Management
27. V.v. Illness Review
28. Wet Storage Tagging

E. Sanitary Transportation of Human and Animal Food
Ken Moore advised Board members that documentation had been furnished in the Board materials. He explained that FDA had asked for ISSC comments. Ken suggested that Board members read the entire regulation. Paul DiStefano informed the Board that the comment deadline had been extended for sixty (60) days until July 30, 2014. Following further discussion, a motion was made that the Executive Director draft comments in response to the regulation and distribute to the Board for comments. The motion was seconded and approved with a voice vote by the Board.

F. NoreCORE
Ken Moore advised that Board members had previously received a copy of the proposed contract with NoreCORE and that he would provide a final copy at the next meeting.

G. Time-Temperature Questions & Answers
Ken Moore advised the Board that as a result of Proposal 11-201B a workgroup had been formed to answer questions concerning interpretation of the new time/temperature requirements. He said these questions and answers will be posted on a designated page on the ISSC website.

IX. OTHER INFORMATION

A. Conference for Food Protection Issue
Julie Henderson reported on the CSPI issue submitted to the CFP which would require retail and restaurants to provide written warning statements if they serve raw oysters. She said the issue did not pass at the CFP Task Force meeting but will be considered at the CFP Executive Board meeting at CFSAN. Following further discussion, Ken advised the Board that he will distribute the issue and make recommendations to the Board on how to address the CFP issue.

B. Proposal 13-202
Mike Hickey presented a question with regard to Proposal 13-202. He said section F. 5. (a) had dropped the word "or" and asked if this was an oversight. Ken Moore explained that the original proposal was submitted by the Executive Office and a substitute was later distributed. Ken said this was an oversight and that this will be discussed with FDA and he will update the Board. He thinks if there is an agreement between ISSC and FDA the language change can be approved by the Board as interim action.

X. EXECUTIVE DIRECTOR ACTIVITIES

Ken Moore reported recent meetings attended and upcoming meetings.

XI. ADJOURN

A motion to adjourn the meeting was made and seconded. The motion carried and the meeting was adjourned at 3:03 PM.

ISSC

Interstate Shellfish Sanitation Conference
209-2 Dawson Road - Columbia, SC 29223
Phone 803-788-7559 - Fax 803-788-7576
Website www.issc.org - Email issc@issc.org

2015 TENTATIVE AGENDA OPTION 1

Saturday

12:00 PM	Business Office Opens
12:00 PM - 4:00 PM	Registration & Selected Committee Meetings
3:00 PM - 3:45 PM	Orientation for New Attendees (Open to Everyone)
4:00 PM - 5:30 PM	Opening General Assembly
6:30 PM - 8:00 PM	Chairman's Welcome Reception

Sunday

8:30 AM - 9:00 AM	Committee Chair Meeting
9:00 AM - 9:00 PM	Committee Meetings

Monday

8:00 AM - 8:30 AM	Executive Board Elections
8:30 AM - 10:30 AM	Executive Board Meeting
10:30 AM - 6:00 PM	Task Force Meetings

Tuesday

8:30 AM - 12:00 PM	Task Force Meetings
1:00 PM - 4:30 PM	Symposium

Wednesday

1:00 PM - 6:00 PM	Task Force Reports Available for Review
7:00 PM - 9:00 PM	Regional Caucuses

Thursday

9:00 AM - 12:00 PM	Closing General Assembly
12:30 PM - 1:30 PM	Executive Board Luncheon
1:30 PM - 4:00 PM	Executive Board Meeting

ISSC

Interstate Shellfish Sanitation Conference
209-2 Dawson Road - Columbia, SC 29223
Phone 803-788-7559 - Fax 803-788-7576
Website www.issc.org - Email issc@issc.org

2015 TENTATIVE AGENDA OPTION 2

Saturday

12:00 PM	Business Office Opens
12:00 PM - 4:00 PM	Registration & Selected Committee Meetings
3:00 PM - 3:45 PM	Orientation for New Attendees (Open to Everyone)
4:00 PM - 5:30 PM	Opening General Assembly
6:30 PM - 8:00 PM	Chairman's Welcome Reception

Sunday

8:30 AM - 9:00 AM	Committee Chair Meeting
9:00 AM - 9:00 PM	Committee Meetings

Monday

8:00 AM - 8:30 AM	Executive Board Elections
8:30 AM - 11:00 AM	Committee Meetings
11:00 AM - 12:30 PM	Executive Board Meeting
1:00 PM - 6:00 PM	Task Force Meetings (consideration of new proposals)

Tuesday

8:30 AM - 6:00 PM	Task Force Meetings

Wednesday

9:00 AM - 12:00 PM	Symposium
1:00 PM - 6:00 PM	Task Force Reports Available for Review
7:00 PM - 9:00 PM	Regional Caucuses

Thursday

9:00 AM - 12:00 PM	Closing General Assembly
12:30 PM - 1:30 PM	Executive Board Luncheon
1:30 PM - 4:00 PM	Executive Board Meeting

Notice of Grant Award

RESEARCH DEMONSTRATION COOPERATIVE AGREEMENTS

Issue Date: 08/12/2014

Department of Health and Human Services
FOOD AND DRUG ADMINISTRATION

Grant Number: 5U18FD004270-04
FAIN: U18FD004270

Principal Investigator:
KEN B MOORE, MA

Project Title: Shellfish Safety Assistance Project

NANCY S. DANIEL
PROGRAM MANAGER
INTERSTATE SHELLFISH SANITATION
209 DAWSON ROAD
COLUMBIA, SC 292231740

Budget Period: 09/01/2014 – 08/31/2015
Project Period: 09/21/2011 – 08/31/2016

Dear Business Official:

The Food and Drug Administration hereby awards a grant in the amount of $325,000 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to INTERSTATE SHELLFISH SANITATION CONF in support of the above referenced project. This award is pursuant to the authority of PHS Act,Sec 1706,42 USC 300u-5,as amended;Sec2(d),PL 98-551 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

If you have any questions about this award, please contact the Grants Management Specialist and the Project Officer listed in the terms and conditions.

Sincerely yours,

Gladys Melendez-Bohler
Grants Management Officer
Office of Acquisitions & Grants Services
Division of Acquisition Support and Grants
Grants & Assistance Team
FOOD AND DRUG ADMINISTRATION

See additional information below

SECTION I – AWARD DATA – 5U18FD004270-04

Award Calculation (U.S. Dollars)

Salaries and Wages	$160,295
Fringe Benefits	$41,205
Personnel Costs (Subtotal)	$201,500
Equipment	$6,000
Supplies	$7,500
Travel Costs	$25,000
Other Costs	$85,000
Federal Direct Costs	$325,000
Approved Budget	$325,000
Federal Share	$325,000
TOTAL FEDERAL AWARD AMOUNT	$325,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$325,000

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$325,000	$325,000
5	$325,000	$325,000

* Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

Fiscal Information:

CFDA Number:	93.103
EIN:	1521656630A1
Document Number:	UFD004270A
Fiscal Year:	2014

IC	CAN	2014	2015
FD	6991782	$265,000	$325,000
FD	69999AG	$60,000	

* Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

FDA Administrative Data:
PCC: CFS3 / **OC**: 414P / **Processed**: ERAAPPS 08/08/2014

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U18FD004270-04

PHS policy requires that you be informed that the DHHS Inspector General maintains a toll free telephone number (800-368-5779) for receiving information concerning fraud, waste and abuse under the grants and cooperative agreements. Such reports will be kept confidential and callers may decline to give their names if they choose to remain anonymous.

Payments under this award will be made available through the DHHS Payment Management System (PMS). PMS is administered by the Division of Federal Assistance Financing (DFAF), Office of the Deputy Assistant Secretary, Finance, which will forward instructions for obtaining payments. Inquiries regarding the payment should be directed to:

Division of Federal Assistance Financing
DASP/DASF/OS/DHHS
P.O. Box 6021
Rockville, MD 20852
Telephone Number: 877-614-5533

Grantees are asked to register in the Central Contractor Registration (CCR) database. Information about CCR is available at http://www.grants.gov/applicants/register_ccr.jsp. This registration will be required as electronic grant processing is implemented.

SECTION III – TERMS AND CONDITIONS – 5U18FD004270-04

This award is based on the application submitted to, and as approved by, FDA on the above-title project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Grant Award.
b. The restrictions on the expenditure of federal funds in appropriations acts to the extent those restrictions are pertinent to the award.
c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
d. The PHS Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. An annual Financial Status Report (SF-269) is required. An original and two copies of this report must be submitted to the FDA Grants Management Officer within 90 days after the expiration date of the budget period.
f. A Final Program Report, Financial Status Report and Invention Statement must be submitted within 90 days after the expiration date of the project period.
g. This award notice, including the terms and conditions cited below.

This award has been assigned the Federal Award Identification Number (FAIN) U18FD004270. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Treatment of Program Income:
Additional Costs

SECTION IV – FD Special Terms and Condition – 5U18FD004270-04

Reporting Requirements:

1. Periodic program monitoring will be conducted which may be in the form of telephone conversations between the Principal Investigator and the Project Officer/Grants Management Officer/Grants Management Specialist. Program monitoring may also be in the form of site visits.

2. A copy of the annual annual Federal Financial Report (SF425) is required. A copy should be provided electronically, via-email, through your organization signing official/Accountant to the FDA Grants Management contact noted below within 90 days after the end of each budget period. It is important that the grantee establish and maintain internal controls to ensure that all FFRs are current, accurate and provide a complete disclosure of the financial status of the project in accordance with 45 CFR Parts 74.1 and 74.53.

3. Annual Non-competing Continuation Program Progress Reports are two months prior to the end of the current budget year. Forms can be accessed at http://grants2.nih.gov/GRANTS/FORMS.HTM These reports must contain the following information:

a. General progress of the project
b. Project status in relation to established timelines.

4. The recipient will conduct, when appropriate, an annual Single Audit as required by OMB Circular A-133. This audit must be submitted to the Federal Audit Clearinghouse at the Bureau of the Census within 9 months of the close of their fiscal year.If you need information on your organization?s obligations under the Single Audit Act, please visit the following website: http://harvester.census.gov/sac/ Valuable information is included under the Frequently Asked Questions section of that site.

Delineation of Substantive Involvement:

FDA will:

1. Appoint a Project Officer or Co-Project Officers who will actively monitor the FDA supported program under this award.
2. Retain the right to have prior approval on the appointment of all key personnel substantially supported by the grant.
3. Be directly involved in the guidance and development of the program and the collaborative structure for the program.
4. Participate with the grantee in determining and carrying out the methodological approaches to be used. Collaboration will also include data analysis, interpretation of findings and where appropriate, co-authorship of publications.
5. Have professional scientific and administrative/clerical personnel working in collaboration with the grantee as required.

Failure to comply with the above stated Standard Terms and Conditions could result in the suspension or termination of this grant project.

For Scientific and Programmatic concerns related to this project contact Paul Distefano 301-402-1410
For Administrative and Financial concerns related to this project contact Gladys Melendez Bohler 402-7565.

This Grant is Excluded from Expanded Authorities.

Direct inquiries regarding scientific programmatic issues to the official listed below.

Direct inquiries regarding fiscal and/or administrative matters to the grants management specialist listed below.

All formal correspondence/reports regarding the grant should be signed by an authorized institutional official and the Principal Investigator and should be sent to the attention of the grants management specialist, unless otherwise explicitly directed.

STAFF CONTACTS
Grants Management Specialist: Gladys Melendez-bohler
Email: gladys.bohler@fda.hhs.gov **Phone**: 240-402-7565 **Fax**: (301) 827-0505

SPREADSHEET SUMMARY
GRANT NUMBER: 5U18FD004270-04

INSTITUTION: INTERSTATE SHELLFISH SANITATION CONF

Budget	Year 4	Year 5
Salaries and Wages	$160,295	$166,015
Fringe Benefits	$41,205	$40,425
Personnel Costs (Subtotal)	$201,500	$206,440
Equipment	$6,000	$7,500
Supplies	$7,500	$8,000

Travel Costs	**$25,000**	**$25,000**
Other Costs	**$85,000**	**$78,060**
TOTAL FEDERAL DC	**$325,000**	**$325,000**
TOTAL FEDERAL F&A		
TOTAL COST	**$325,000**	**$325,000**

Food & Drug Administration	DATE June 17, 2014 1. CENTER/PROGRAM CFSAN
2. LIST NUMBER FD-004270-03	3. APPROPRIATION NUMBER 75140600
4. CAN* 6991782 TAG# 5199OFS406A1974 (CFSAN) $265,000 69999AG TAG# 122023X24835NOA (NOAA) $60,000	5. PMS CODE* 223151/10
6. OBJECT CLASS 41.41	7. TYPE OF AWARD Non - Competing – Research

8. GRANT NUMBER	9. Document #	10: EIN#
5U18-FD004270-04	UFD004270A	1521656630A1

Ken Moore
Interstate Shellfish Sanitation
209 Dawson Road – Suite 2
Columbia, SC 29223-1740

12. PROJECT PERIOD	13. BUDGET PERIOD
09/21/2011-08/31/2016	09/01/2014-08/31/2015

14. APPROVED FOR OBLIGATION

DIRECT: $ 325,000 INDIRECT: $O $ FEE: $0 (SBIR ONLY) TOTAL COST:$325,000

15. SPECIAL CONDITIONS

- Please provide Terms and Conditions of Award in addition to those already attached to the award.
- Please provide requisition number

· Requisition: 1137445
· Conf Code: 370

16. REMARKS

Please scan the signed document to G. Bohler – gladys.bohler@fda.hhs.gov

- 240-402-7566 – Telephone
- 301-827-0505 – FAX

17. PROJECT OFFICER (Print name and Sign; provide telephone #)	18. CENTER/OFFICE
Phone Number: Paul Distefano, 240-402-1410	Funds Available: Alexander Hawkins, Budget Director, CFSAN

19. APPROVED BY DIRECTOR, (or individual with Delegated Authority)

Brian Trent, Associate Director for Management, CFSAN

20. APPROVED BY DIRECTOR, OFFICE OF FINANCIAL MANAGEMENT

21. CERTIFICATION OF Chief GRANTS MANAGEMENT OFFICER, OAGS and/or Grants Management Officer

Gladys Melendez (Bohler) 8/11/14

Form FDA 3349 (2/97)

Notice of Grant Award

RESEARCH DEMONSTRATION COOPERATIVE AGREEMENTS
Department of Health and Human Services
FOOD AND DRUG ADMINISTRATION

Issue Date: 09/08/2014

Grant Number: 3U18FD004270-04W1
FAIN: U18FD004270

Principal Investigator:
KEN B MOORE, MA

Project Title: Shellfish Safety Assistance Project

NANCY S. DANIEL
PROGRAM MANAGER
INTERSTATE SHELLFISH SANITATION
209 DAWSON ROAD
COLUMBIA, SC 292231740

Budget Period: 09/01/2014 – 08/31/2015
Project Period: 09/21/2011 – 08/31/2016

Dear Business Official:

The Food and Drug Administration hereby awards a grant in the amount of $75,000 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to INTERSTATE SHELLFISH SANITATION CONF in support of the above referenced project. This award is pursuant to the authority of PHS Act,Sec 1706,42 USC 300u-5,as amended;Sec2(d),PL 98-551 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

If you have any questions about this award, please contact the Grants Management Specialist and the Project Officer listed in the terms and conditions.

Sincerely yours,
Gladys M. Bohler
Gladys Melendez-Bohler
Grants Management Officer
Office of Acquisitions & Grants Services
Division of Acquisition Support and Grants
Grants & Assistance Team
FOOD AND DRUG ADMINISTRATION

See additional information below

SECTION I – AWARD DATA – 3U18FD004270-04W1

Award Calculation (U.S. Dollars)

Federal Direct Costs	$75,000
Approved Budget	$75,000
Federal Share	$75,000
TOTAL FEDERAL AWARD AMOUNT	$75,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$75,000

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (4)	
GRANT NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
3U18FD004270-04W1	$75,000
5U18FD004270-04	$325,000
TOTAL	**$400,000**

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$75,000	$400,000
5	$0	$325,000

* Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

Fiscal Information:

CFDA Number:	93.103
EIN:	1521656630A1
Document Number:	UFD004270A
Fiscal Year:	2014

IC	CAN	2014
FD	6991782	$75,000

* Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

FDA Administrative Data:
PCC: CFS3 / **OC**: 414N / **Processed**: ERAAPPS 08/28/2014

SECTION II – PAYMENT/HOTLINE INFORMATION – 3U18FD004270-04W1

PHS policy requires that you be informed that the DHHS Inspector General maintains a toll free telephone number (800-368-5779) for receiving information concerning fraud, waste and abuse under the grants and cooperative agreements. Such reports will be kept confidential and callers may decline to give their names if they choose to remain anonymous.

Payments under this award will be made available through the DHHS Payment Management System (PMS). PMS is administered by the Division of Federal Assistance Financing (DFAF), Office of the Deputy Assistant Secretary, Finance, which will forward instructions for obtaining payments. Inquiries regarding the payment should be directed to:

Division of Federal Assistance Financing
DASP/DASF/OS/DHHS
P.O. Box 6021

Rockville, MD 20852
Telephone Number: 877-614-5533

Grantees are asked to register in the Central Contractor Registration (CCR) database. Information about CCR is available at http://www.grants.gov/applicants/register_ccr.jsp. This registration will be required as electronic grant processing is implemented.

SECTION III – TERMS AND CONDITIONS – 3U18FD004270-04W1

This award is based on the application submitted to, and as approved by, FDA on the above-title project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Grant Award.
b. The restrictions on the expenditure of federal funds in appropriations acts to the extent those restrictions are pertinent to the award.
c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
d. The PHS Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. An annual Financial Status Report (SF-269) is required. An original and two copies of this report must be submitted to the FDA Grants Management Officer within 90 days after the expiration date of the budget period.
f. A Final Program Report, Financial Status Report and Invention Statement must be submitted within 90 days after the expiration date of the project period.
g. This award notice, including the terms and conditions cited below.

This award has been assigned the Federal Award Identification Number (FAIN) U18FD004270. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Treatment of Program Income:
Additional Costs

SECTION IV – FD Special Terms and Condition – 3U18FD004270-04W1

PLEASE NOTE: This award reflects an administrative supplement in the amount of $75,000. Funds are to be used for the purposes stated below and as provided by e-mail on 8/8/2014 to Nancy Daniel:

Funds to support this Administrative Supplement have been obligated by the Center for Food Safety and Applied Nutrition, Office of Food Safety and shall be used for the purpose of awarding and administering research projects that will advance the science of *Vibrios* and the efficacy of various *Vibrio* control strategies as well as to collect and analyze data and information associated with state and industry Vibrio control efforts. The work will further inform existing goals set forth in the current FDA/ISSC *Shellfish Safety Assistance Agreement* (Grant Number U18FD004270).

Reporting Requirements:

1. Periodic program monitoring will be conducted which may be in the form of telephone conversations between the Principal Investigator and the Project Officer/Grants Management Officer/Grants Management Specialist. Program monitoring may also be in the form of site visits.

2. A copy of the annual annual Federal Financial Report (SF425) is required. A copy should be provided electronically, via-email, through your organization signing official/Accountant to the FDA Grants Management contact noted below within 90 days after the end of each budget period. It is important that the grantee establish and maintain internal controls to ensure that all FFRs are current, accurate and provide a complete disclosure of the financial status of the project in accordance with 45 CFR Parts 74.1 and 74.53.

3. Annual Non-competing Continuation Program Progress Reports are two months prior to the end of the current budget year. Forms can be accessed at http://grants2.nih.gov/GRANTS/FORMS.HTM These reports must contain the following information:

a. General progress of the project
b. Project status in relation to established timelines.

4. The recipient will conduct, when appropriate, an annual Single Audit as required by OMB Circular A-133. This audit must be submitted to the Federal Audit Clearinghouse at the Bureau of the Census within 9 months of the close of their fiscal year.If you need information on your organization?s obligations under the Single Audit Act, please visit the following website: http://harvester.census.gov/sac/ Valuable information is included under the Frequently Asked Questions section of that site.

Delineation of Substantive Involvement:

FDA will:

1. Appoint a Project Officer or Co-Project Officers who will actively monitor the FDA supported program under this award.
2. Retain the right to have prior approval on the appointment of all key personnel substantially supported by the grant.
3. Be directly involved in the guidance and development of the program and the collaborative structure for the program.
4. Participate with the grantee in determining and carrying out the methodological approaches to be used. Collaboration will also include data analysis, interpretation of findings and where appropriate, co-authorship of publications.
5. Have professional scientific and administrative/clerical personnel working in collaboration with the grantee as required.

Failure to comply with the above stated Standard Terms and Conditions could result in the suspension or termination of this grant project.

For Scientific and Programmatic concerns related to this project contact Paul Distefano 301-402-1410
For Administrative and Financial concerns related to this project contact Gladys Melendez Bohler 240-402-7565.

This Grant is Excluded from Expanded Authorities.

Direct inquiries regarding scientific programmatic issues to the official listed below.

Direct inquiries regarding fiscal and/or administrative matters to the grants management specialist listed below.

All formal correspondence/reports regarding the grant should be signed by an authorized institutional official and the Principal Investigator and should be sent to the attention of the grants management specialist, unless otherwise explicitly directed.

STAFF CONTACTS
Grants Management Specialist: Gladys Melendez-bohler
Email: gladys.bohler@fda.hhs.gov **Phone**: 240-402-7565 **Fax**: (301) 827-0505

SPREADSHEET SUMMARY
GRANT NUMBER: 3U18FD004270-04W1

4270

Food & Drug Administration	DATE 5/22/2014 1. CENTER/PROGRAM CFSAN
2. LIST NUMBER FD-004270-03	3. APPROPRIATION NUMBER 75140600
4. CAN* CAN NO. 6991782 TAG NO. 5184OFS405K1152	5. PMS CODE* 223151/10
6. OBJECT CLASS 41.41	7. TYPE OF AWARD Non - Competing – Research

8. GRANT NUMBER	9. Document #	10: EIN#
3U18-FD004270-03S1	UFD004270A	1521656630A1

Ken Moore
Interstate Shellfish Sanitation
209 Dawson Road – Suite 2
Columbia, SC 29223-1740

12. PROJECT PERIOD	13. BUDGET PERIOD
09/21/2011-08/31/2016	09/01/2013-08/31/2014

14. APPROVED FOR OBLIGATION

DIRECT: $ 75,000 INDIRECT: $O $ FEE: $0 (SBIR ONLY) TOTAL COST:$75,000

15. SPECIAL CONDITIONS

- Please provide Terms and Conditions of Award in addition to those already attached to the award.

Requisition 1135113
Ref code 370

16. REMARKS

Please scan the signed document to G. Bohler – gladys.bohler@fda.hhs.gov

- 301-827-7175 – Telephone
- 301-827-0505 – FAX

17. PROJECT OFFICER (Print name and Sign; provide telephone #)	18. CENTER/OFFICE
Phone Number: Paul W. Distefano 240-402-1410	Funds Available: Alexander Hawkins, Budget Director, CFSAN

19. APPROVED BY DIRECTOR, (or individual with Delegated Authority)

Brian Trent, Associate Director for Management, CFSAN

20. APPROVED BY DIRECTOR, OFFICE OF FINANCIAL MANAGEMENT

21. CERTIFICATION OF Chief GRANTS MANAGEMENT OFFICER, OAGS and/or Grants Management Officer

Gladys Melendez (Bohler)

Form FDA 3349 (2/97)

_V.p._ Illness Guidance Committee
September 3, 2014 Conference Call
Meeting Report

Committee Chair:	Maryanne Guichard	
Committee Members Present:	Bob Rheault	Eric Hickey
	Jerrod Davis	Kirk Wiles
	Lori Howell	Margaret Barrette
	Paul Distefano	Andy Depaola

Findings: The *V.p.* Illness Guidance Committee had a discussion to develop guidance for Model Ordinance Chapter II @ .02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)*

Recommendation 1:

The Committee recommends that the ISSC Executive Board adopt interim approval of the following guidance document.

Guidance Document for *V.p.* Illness Response

I. Introduction

Chapter II @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (*V.p.*) is intended to address three (3) distinct *V.p.* illness situations as follows:

A. Traditional sporadic cases from a State in which single cases occur that most often do not involve a single growing area and occur weeks or months apart. The occurrences of these types of illnesses have historically been considered as an acceptable risk in the National Shellfish Sanitation Program (NSSP) and have not involved closures or recalls.

B. Frequent sporadic cases which often begin when water temperatures reach a level which supports reproduction of *V.p.* to levels which can cause illness. The illness risk usually persists until the environmental conditions no longer support *V.p.* levels of illness causing potential. This illness situation involves clusters of sporadic cases in multiple individual growing areas or may be limited to a single growing area when the environmental conditions are favorable for the persistence of illness causing levels of *V.p.*

C. A true outbreak with multiple cases with multiple harvest areas and varying routes of transportation indicates a more widespread contamination of a growing area. The outbreak may be characterized by a high attack rate. In this situation, a single growing area is usually involved with multiple cases of illness occurring from a single harvest day or from a relatively short harvest time frame.

The strains of *V.p.* associated with these different illness situations are not the same. The attack rates are very different and the reported illnesses reflect the differences in attack

rates. Although strain identification is time consuming, knowing the strain aids the State Shellfish Control Authority in addressing the problem.

II. Illness Investigation

When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and the span of time.

The State Shellfish Control Authority is encouraged to coordinate the investigation and response with other appropriate State entities and the US Food and Drug Administration (FDA) to facilitate and streamline the reporting process to promote prompt and appropriate regulatory responses to illness.

III. Risk per Serving Determinations

In determining a risk per serving, the State Shellfish Control Authority should use a recognized serving size and credible landing data. The period of time for evaluating the risk per serving should be consistent with the time of harvest of the shellfish that was associated with the illness (es) and should not exceed thirty (30) days

IV. Regulatory Response

When a case(s) is reported, the State Shellfish Control Authority will determine the number of cases and the time period between the harvest dates of reported cases and the extent of the implicated area.

When determining the number of illnesses in the thirty (30) day period, the harvest date will be used. When an illness occurs, the State Shellfish Control Authority will determine the number of cases that have occurred during the previous thirty (30) days. Every subsequent harvest associated with a new reported case will require a review of the previous thirty (30) days.

A. Should the number of cases and the period of time result in a risk that is less than one (1) per 100,000 servings or involves at least two (2) but not more than four (4) cases in which no two of these were from a single harvest day from an implicated area, the State Shellfish Control Authority will evaluate and attempt to ensure compliance, where appropriate, with the existing Vibrio Management Plan. Regulatory response to multiple illnesses occurring from a single harvest day from an implicated area is addressed in IV. B. and IV. C.

B. Should the number of cases and the period of time result in a risk that exceeds one (1) illness per 100,000 servings or if the number of cases within a thirty (30) day period from the implicated area is more than four (4) but less than ten (10) or if two (2) or more but

less than four (4) cases occur from a single harvest day from the implicated area, the State Shellfish Control Authority is required to:

(1) Determine the extent of the implicated area; and
(2) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and
(3) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish

The notification is intended to facilitate the reporting of other illnesses that may have occurred associated with the implicated harvest area. Although the State is not required to report this information to the Interstate Shellfish Sanitation Conference (ISSC), if requested, the ISSC will assist the States with notification.

C. Should the number of cases exceed ten (10) within a thirty (30) day period or four (4) or more cases occurred from a single harvest day from the implicated area, the State Shellfish Control Authority is required to:

(1) Determine the extent of the implicated area; and
(2) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and
(3) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products; and
(4) Issue a consumer advisory for all shellfish (or species implicated in the illness).

The consumer advisory shall be in the form of a news release and will be shared with the State Shellfish Control Authorities in all states receiving the implicated shellfish.

V. Closure Periods

A. When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area the State Shellfish Control Authority will close the implicated growing area. The area will remain closed for a minimum of fourteen (14) days.

B. When the number of cases exceeds ten (10) illnesses within thirty (30) days or four (4) cases occur from a single harvest date from the implicated area the State Shellfish Control Authority will close the implicated growing area. The area will remain closed for a minimum of twenty-one (21) days.

VI. Reopening of Closed Areas

Prior to reopening an area closed as a result of the number of cases exceeding ten (10) illnesses within thirty (30) days or four (4) cases from a single harvest date from the implicated area, the Authority shall:

A. Collect and analyze samples to ensure that tdh does not exceed 10/g and trh does not exceed 10/g or other such values as determined appropriate by the Authority based on studies.

B. Ensure that environmental conditions have returned to levels not associated with *V.p.* cases.

C. Implicated areas that have been closed when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area do not require sampling or review of environmental conditions prior to reopening.

VII. Harvesting From Closed Areas

Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one or more of the following controls:

A. Post-harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and/or hard clams and a three (3) log reduction for Pacific Coast oysters and/or hard clams;

B. Restricting oyster and/or hard 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;

C. Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.

VIII. Laboratory

All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA Shellfish Laboratory Evaluation Office or FDA certified State Shellfish Laboratory Evaluation Officer in accordance with the requirements established under the NSSP.

IX. Approved Laboratory Methods

Methods for the analyses of shellfish and shellfish growing or harvest waters shall be:

The Approved NSSP Methods validated for use in the National Shellfish Sanitation

Program under Procedure XVI. of the Constitution, Bylaws and Procedures of the ISSC and/or cited in the NSSP Guide for the Control of Molluscan Shellfish Section IV Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests.

Laboratory and Approved Laboratory Methods Note:

Many laboratories that are presently providing support to states have not been evaluated. These laboratories in most cases are using unapproved methods. These methods are cost effective and require less time for results. The ISSC Executive Board will discuss steps necessary to allow the use of unapproved laboratories and unapproved laboratory methods.

Recommendation 2:

The Committee recommends that the ISSC Executive Board approve the following modifications to Model Ordinance Chapter II. @ .02:

1. Chapter II. @ .02 A. (4):

(4) When a growing area has been closed as a result of *V.p.* cases, the Authority shall keep the area closed for the following periods of time to determine if additional illnesses have occurred:

~~(a) The area will remain closed for a minimum of seven (7) days when sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves four (4) or less cases occurring within a thirty (30) day period from the implicated area in which no two (2) cases occurred from a single harvest date from the implicated area.~~

~~(b)~~(a) The area will remain closed for a minimum of fourteen (14) days when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area.

~~(c)~~(b) The area will remain closed for a minimum of twenty-one (21) days when the number of cases exceeds ten (10) illnesses within thirty (30) days or four (4) cases occur from a single harvest date from the implicated area

2. Chapter II. @ .02 A. (5):

(5) Prior to reopening an area closed as a result of the number of cases exceeding ten (10) illnesses within thirty (30) days or four (4) cases from a single harvest date from the implicated area, the Authority shall:

(a) Collect and analyze samples to ensure that tdh does not exceed 10/g and trh does not exceed 10/g; or other such values as determined appropriate by the Authority based on studies; or~~.~~

(b) Ensure that environmental conditions have returned to levels not associated with *V.p.* cases.

C. The Committee recommends that the ISSC Executive Board discuss steps necessary to allow the use of or adopt interim approval for unapproved laboratories and unapproved laboratory methods that are currently being used to assist States.

D. The Committee recommends that a workgroup be formed to define "Implicated Area" as used in Model Ordinance Chapter II. @ .02 for use in the Guidance Document for *V.p.* Illness Response.

Conflict of Interest Statement

The Interstate Shellfish Sanitation Conference, all Officers and Directors, shall avoid any conflict between their own respective personal, professional or business interests and the interests of the Conference, in any and all actions taken by them on behalf of their respective capacities.

In the event that any Officer or Board Member of the Conference shall have any direct or indirect interest in, or relationship with, any individual or organization which proposes to enter into any transaction with the Conference, including but not limited to transactions involving:

a. employment, or rendition of services, personal or otherwise;

b. the award of any grant, contracts, or subcontracts;

c. the investment or deposit of any funds of this Conference;

such person shall give notice of such interest or relationship and shall thereafter refrain from discussing or voting on the particular transaction in which he has an interest, or otherwise attempting to exert any influence on the Conference, or its components to affect a decision to participate or not participate in such transaction.

For the purposes of this Statement, a member has a conflict of interest when the member exercises an official power or performs an official duty or function in the execution of his or her office and at the same time knows that in the performance of the duty or function or in the exercise of the power there is an opportunity to further his or her private interest.

For the purposes of this Statement, a member has an apparent conflict of interest if there is a reasonable perception, which a reasonably well informed person could properly have, that the member's ability to exercise an official power or perform an official duty or function must have been affected by his or her private interest.

This Statement is intended to supplement but not replace any applicable State laws governing conflicts of interest applicable to nonprofit and charitable corporations.

Date: _____ Signed: _____

Print Name: _____

From: ISSC
To: "regulations@cdph.ca.gov"
Bcc: ISSC; Nancy Daniel
Subject: DPH-06-006
Date: Monday, August 11, 2014 3:55:00 PM

August 11, 2014

Comments on:

Notice of Proposed Rulemaking
Title 17
California Code of Regulations
Raw Gulf Oysters
DPH-06-006
Notice Published June 27, 2014

The Interstate Shellfish Sanitation Conference (ISSC) has reviewed the Notice of Proposed Rulemaking referenced above which was issued on June 27, 2014. The ISSC applauds and appreciates the efforts of the California Department of Public Health to amend the regulation to achieve consistency with the National Shellfish Sanitation Program (NSSP) guidelines for post-harvest processing (PHP) validation. The ISSC supports the findings, conclusions, and recommended PHP validation changes which will eliminate an unnecessary cost to companies that are presently shipping post-harvest processed shellfish to the State of California.

If the ISSC can be of any assistance to the California Department of Public Health in your rule making process, please advise me.

Ken B. Moore, Executive Director
Interstate Shellfish Sanitation Conference

Ken B. Moore, Executive Director
Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223-1740

Phone: 803-788-7559
Fax: 803-788-7576
Email: issc@issc.org
Website: www.issc.org

JUN 30 2014

State of California—Health and Human Services Agency
California Department of Public Health

RON CHAPMAN, MD, MPH
Director & State Health Officer

EDMUND G. BROWN JR.
Governor

NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations
Raw Gulf Oysters, DPH-06-006
Notice Published June 27, 2014

PUBLIC PROCEEDINGS

The California Department of Public Health (Department) is conducting a written public proceeding during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement Overview section of this notice.

PUBLIC HEARING

The Department has not scheduled a public hearing on this proposed action. However, the department will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days before the close of the written comment period.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Department. The written comment period closes at 5:00 p.m. on August 11, 2014. The Department will consider only comments received at the Department's Office of Regulations at that time.

Written comments may be submitted as follows:

1. By email to regulations@cdph.ca.gov. Please place the regulation package identifier "DPH-06-006" in the subject line;

2. By fax transmission to (916) 440-5747;

3. By postal service to Office of Regulations, California Department of Public Health, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377; or,

4. Hand-delivered to Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All comments, including email or fax transmissions, should include the author's name and U.S. Postal Service mailing address.

AUTHORITY AND REFERENCE

This rulemaking action implements, interprets, and makes specific the California statutes associated with providing consumer warnings about the risks associated with consumption of Gulf oysters that may contain the bacterium, *Vibrio vulnificus (V. vulnificus),* sales restrictions, warning exemptions, and procedural verifications for raw Gulf oysters processed to reduce *V. vulnificus*. The statutory authorities cited for this regulatory proposal are found in Health and Safety Code Sections 110065, 110105, 110430, 112165, 113707, 131050, 131051, 131052, 131055, 131056, and 131200. The references cited in this regulatory proposal are Health and Safety Code Sections 110175, 110435, 110545, 110560, 110565, 110660, 110705, 112165(c), 112195, 112200, 113980, 114029, 114039, 114039.1, 114039.2, 114039.3, 114039.4, and 131071.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Department is authorized to establish and enforce regulations pertaining to certain health and safety concerns associated with raw Gulf of Mexico (Gulf) oysters in California, pursuant to HSC Sections 109875, 110105, 112150, and 113700.

This rulemaking action implements, interprets, and makes specific the California health and safety statutes that provide consumer warnings about the risks associated with the consumption of Gulf oysters that may contain the *V. vulnificus,* sales restrictions, warning exemptions, and procedural verifications for post-harvest processed Gulf oysters processed to reduce *V. vulnificus*. The purpose of this proposal is to amend subsections 13675(a)(8) and 13676(a)(4), Title 17, of the California Code of Regulations (CCR). The proposed amendment to subsection 13675(a)(8) revises the microbiological level for *V. vulnificus* in post-harvest processed Gulf oysters from the current level of less than 3 Most Probable Number per gram (MPN/g) to less than 30 MPN/g. This amendment will require that the less than 30 MPN/g level of *V. vulnificus* is met through a performance standard that achieves a minimum 3.52 log reduction. The proposed amendment to subsection 13675(a)(8) also revises the laboratory procedures employed for the detection and enumeration of *V. vulnificus* in post-harvest processed oysters to be consistent with the revised microbiological level. The proposed amendments to CCR subsection 13676(a)(4) make its wording consistent with the amendments to CCR Section 13675.

These proposed amendments harmonize California's molluscan shellfish regulations with the provisions adopted for the National Shellfish Sanitation Program (NSSP) by the U.S. Food and Drug Administration (FDA) and Interstate Shellfish Sanitation Conference (ISSC). With the exception of California, all member states and countries of ISSC have adopted the less than 30 MPN/g microbiological level for *V. vulnificus* in post-harvest processed oysters.

The proposed regulatory amendments are consistent with the findings of risk determined by the Food and Agriculture Organization of the World Health Organization (FAO/WHO). The findings are also supported by epidemiological data maintained by the FDA. Since becoming commercially available in 2005, there have been no epidemiologically-linked *V. vulnificus* infections associated with raw oysters processed at the less than 30 MPN/g level documented by the FDA.

These proposed regulatory amendments will likely result in the removal of sanctions against California by ISSC and avert the negative economic impact to California

businesses that may result from additional administrative actions that may be assessed on California by ISSC and the FDA. In addition, the amendments provide the Department with the authority to uniformly regulate raw oysters processed to less than 30 MPN/g, but harvested during different times of the year. This proposal maintains the current level of restriction on the sale of raw[1] Gulf oysters harvested from the states of Alabama, Florida, Louisiana, Mississippi, or Texas during April through October. Additional benefits anticipated by the Department include a reduction of costs associated with processing oysters using certain technologies and an increase in the amounts and varieties of post-harvest processed oysters imported into California to the benefit of consumers.

OBJECTIVES

The broad objectives of this regulatory proposal are:

- To harmonize California's molluscan shellfish regulations for post-harvest processed Gulf oysters with those of the NSSP, as adopted by the FDA and ISSC. The proposed revised standard is based on the determinations of the *Vv* Risk Assessment conducted by the FAO/WHO. With the exception of California, all member states and countries of ISSC have adopted the less than 30 MPN/g microbiological level for *V. vulnificus* in post-harvest processed oysters.

- To provide a science-based standard for post-harvest processed oysters based on a risk assessment conducted by the FAO/WHO.

- To provide for uniform regulatory enforcement for post-harvest processed oysters by allowing the sale of Gulf oysters, processed to less than 30 MPN/g, to be sold year-round, irrespective of harvest date.

- To provide clarity and consistency for the public and the oyster industry regarding oyster health and safety regulations.

- To establish performance-based health and safety standards that meet concerns of public health officials, the public, and shellfish dealers.

- To protect the public health and safety of California consumers of oysters using scientific-based standards.

BENEFITS

The anticipated major benefits, including nonmonetary benefits such as the protection of public health and safety, worker safety, the environment, the prevention of discrimination, or the promotion of fairness or social equity, and the increase in transparency in business and government among other things, from this proposed regulatory action include:

- To harmonize California's molluscan shellfish regulations for post-harvest processed Gulf oysters with those of the NSSP, as adopted by the FDA and ISSC. The proposed revised standard is based on the determinations of the *Vv* Risk Assessment conducted the FAO/WHO. With the exception of California, all member

[1] When originally promulgated, CCR Section 13675 was directed at reducing the illness from the consumption of raw oysters that had not been processed to reduce pathogens such as *V. vulnificus*. Post-harvest processed oysters are regulated as raw, but have been subjected to a process to reduce levels of targeted *V. vulnificus*.

states and countries of ISSC have adopted the less than 30 MPN/g microbiological level for *V. vulnificus* post-harvest processed oysters.

- To establish performance-based health and safety standards, using scientific research that meet concerns of public health officials, the public, and shellfish dealers.
- To provide for uniform regulatory enforcement for post-harvest processed oysters by allowing the sale of Gulf oysters, processed to less than 30 MPN/g, to be sold year-round, irrespective of harvest date.
- To allow the Department to petition the ISSC to remove current administrative sanctions against California.
- To prevent the imposition of administrative actions by the FDA to remove California shellfish dealers from the ICSSL. This will avert economic harm to California shellfish dealers and allow for the unrestricted sale of shellfish into interstate commerce by California dealers.
- To potentially reduce the costs to treat oysters post-harvest.
- To potentially provide greater amounts and varieties of oysters processed for enhanced safety for the culinary enjoyment of Californians, especially those who are high-risk for infection.
- To reduce confusion for the public and the oyster industry about oyster health and safety restrictions.
- To assist the efforts of the FDA and the ISSC in their efforts to promote oyster post-harvest treatment technologies to provide additional choices to high-risk individuals nationwide.
- To protect the public health and safety of California consumers of oysters using scientifically-derived standards.

INCONSISTENT/INCOMPATIBLE WITH EXISTING STATE REGULATIONS

The Department evaluated whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing general regulations and those regulations specific to food health and safety, specifically the regulating of oysters. An internet search of other state agency regulations was also performed. It was determined that no other regulation addressed the same subject matter, and that this proposal was not inconsistent or incompatible with other state regulations. Therefore, it is determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations.

MANDATED BY FEDERAL LAW OR REGULATIONS

Currently, there are no existing federal regulations or statutes applicable to the regulations.

states and countries of ISSC have adopted the less than 30 MPN/g microbiological level for *V. vulnificus* post-harvest processed oysters.

- To establish performance-based health and safety standards, using scientific research that meet concerns of public health officials, the public, and shellfish dealers.
- To provide for uniform regulatory enforcement for post-harvest processed oysters by allowing the sale of Gulf oysters, processed to less than 30 MPN/g, to be sold year-round, irrespective of harvest date.
- To allow the Department to petition the ISSC to remove current administrative sanctions against California.
- To prevent the imposition of administrative actions by the FDA to remove California shellfish dealers from the ICSSL. This will avert economic harm to California shellfish dealers and allow for the unrestricted sale of shellfish into interstate commerce by California dealers.
- To potentially reduce the costs to treat oysters post-harvest.
- To potentially provide greater amounts and varieties of oysters processed for enhanced safety for the culinary enjoyment of Californians, especially those who are high-risk for infection.
- To reduce confusion for the public and the oyster industry about oyster health and safety restrictions.
- To assist the efforts of the FDA and the ISSC in their efforts to promote oyster post-harvest treatment technologies to provide additional choices to high-risk individuals nationwide.
- To protect the public health and safety of California consumers of oysters using scientifically-derived standards.

INCONSISTENT/INCOMPATIBLE WITH EXISTING STATE REGULATIONS

The Department evaluated whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing general regulations and those regulations specific to food health and safety, specifically the regulating of oysters. An internet search of other state agency regulations was also performed. It was determined that no other regulation addressed the same subject matter, and that this proposal was not inconsistent or incompatible with other state regulations. Therefore, it is determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations.

MANDATED BY FEDERAL LAW OR REGULATIONS

Currently, there are no existing federal regulations or statutes applicable to the regulations.

FORMS INCORPORATED BY REFERENCE
Not applicable.

OTHER STATUTORY REQUIREMENTS
Not applicable.

LOCAL MANDATE
The Department has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

FISCAL IMPACT ESTIMATE

A. Fiscal Effect on Local Government or School District: None.

B. Fiscal Effect on State Government: Yes. The Department anticipates potentially reviewing and approving approximately 9 shellfish processing applications the first year and unknown number subsequent fiscal years. The application review is not a new program or increasing the scope of the existing program nor will these applications necessary be submitted and the costs incurred. The Department is not aware of any other cost impacts that State government would necessarily incur in reasonable compliance with the proposed action.

C. Fiscal Effect on Federal funding of state programs: None.

D. Other nondiscretionary cost or savings imposed on local agencies: There are no known costs or savings imposed on local agencies in connection with this proposed regulatory package.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSON OR BUSINESS
The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

HOUSING COSTS
The Department has determined that the proposed regulations will not have a financial impact on housing.

SIGNIFICANT, STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING THE ABILITY OF CALIFORNIA BUSINESSES TO COMPETE WITH BUSINESSES IN OTHER STATES
The Department has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

SMALL BUSINESS
This regulatory proposal does not impact most small businesses in California as defined by Government Code Section 11342.610. The Department has determined that there may be, however, a financial benefit for some shellfish small businesses as a result of adopting this regulatory proposal. California businesses may sell more oysters by being able to sell greater amounts and varieties of oysters, processed to less than 30 MPN/g, year-round,

irrespective of the harvest date. The Department anticipates that this regulatory proposal will prevent the imposition of administrative sanctions by the FDA, such as removing California shellfish dealers from the ICSSL that would negatively impact some small businesses. This regulatory proposal will also avert economic harm to California shellfish dealers by allowing the unrestricted sale of oyster into interstate commerce by California dealers. In addition, it is possible some businesses may reduce treatment costs due to performance-based treatment technologies.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS/ASSESSMENT

Based on the economic impact analysis, the Department has determined that the regulation would not significantly affect the following:

1. The creation or elimination of jobs within the State of California.
2. The creation of new businesses or the elimination of existing businesses within the State of California.
3. The expansion of businesses currently doing business within the State of California.
4. The benefits of the regulations to the health and welfare of California residents, worker safety, and the state's environment.

Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The proposed regulations are reasonably necessary to protect the health and welfare of California consumers of raw oysters.

BUSINESS REPORTING REQUIREMENT

No Report Required.

ALTERNATIVES INFORMATION

As to these proposed regulations and in accordance with Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the regulatory action is proposed, would be as effective and less burdensome to affected private persons than the proposed regulatory action; or, would be more cost effective to affected private persons, and equally effective in implementing the intent of the statutory policy or other provision of law. Alternatives considered in this proposal are addressed in the Initial Statement of Reasons.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations during the written comment period.

CONTACT PERSON

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Pat Kennelly, Chief, Food and Drug Branch, Food Safety Section, at (916) 650-6598.

All other inquiries concerning this notice may be directed to Laurel Prior, Office of Regulations, at (916) 440-7673.

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS, AND RULEMAKING FILE

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents, please call (916) 440-7673 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Materials regarding the action described in this notice (including this public notice, the regulation text of the proposed regulations, and the initial statement of reasons) are available via the Internet and may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending & Opportunity for Public Participation, Proposed Regulations.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

Kathleen Balenglay for Dr. Ron Chapman

Date:

Ron Chapman, MD, MPH
Director and State Health Officer

[X] New
[ ] Modification No. ___

NCSU Subaward Number 2011-0494-20

Subaward Notice (SN)

SUBRECIPIENT	NCSU
1. INTERSTATE SHELLFISH SANITATION CONFERENCE (ISSC) 209-S DAWSON ROAD COLUMBIA, SC 29223-1740	2. **NORTH CAROLINA STATE UNIVERSITY** Sponsored Programs & Regulatory Compliance Services Campus Box 7514 2701 Sullivan Drive, Suite 240 Raleigh, NC 27695-7514
3. **Proposal/Project Title** Building Capacity to Control Viral Foodborne Disease: A Translational, Multidisciplinary Approach	4. **Source of Funding:** Prime Sponsor: US DEPT OF AG (USDA) Prime Agreement Number: HR 03-113 CFDA: Title: Building Capacity to Control Viral Foodborne Disease: A Translational, Multidisciplinary Approach
5. **Description/Purpose of This Action:.** To issue a subcontract to INTERSTATE SHELLFISH SANITATION CONFERENCE (ISSC) in the amount of $99,949. (PMR#712)	
6. **Special Terms and Conditions:**	7. **Funding Information / Period of Performance:**
	a. Amount Funded This Action: **$103,345**
	b. Amount Prior Funding: $0
	c. Total Sponsored Funds To Date: **$103,345**
	d. Cost-sharing Added with This Action: $
	e. Total Cost Sharing Required To Date: $
	f. Start Date: 09/01/2013
☐ Special T&C Continued in Block 17, page 2	g. End Date: 05/31/2014
Each signatory below certifies that they are authorized to execute legally binding commitments on behalf of their named party.	
For: **INTERSTATE SHELLFISH SANITATION CONFERENCE (ISSC)** Signature: _____ Name & Title: Date: _____ **TIN/EIN: 521656630** **DUNS: 837518281**	For: **NORTH CAROLINA STATE UNIVERSITY** Signature: _____ Name & Title: Date: _____

[X] New

NCSU Subaward Number 2011-0494-20 [ ] Modification No. ___

(Subaward Notice Continued) Contact Information

The parties agree that pen and ink entries to correct or update the information in Blocks 10-15 are not "changes" requiring initials.

SUBRECIPIENT	NORTH CAROLINA STATE UNIVERSITY
8. **Principal Investigator:** Name: Ken Moore Phone: 803-788-7559 Fax: 803-788-7576 Email: issc@issc.org	9. **Project Director:** Name: Lee-Ann Jaykus Phone: 919-513-2074 Fax: Email: leeann_jaykus@ncsu.edu
10. **Negotiator / Administrator:** Name: Same as Box# 8 Phone: Fax: Email: Address: 209-2 Dawson Road Columbia, SC 29223-1740	11. **Negotiator / Administrator:** Name: Lara Shields Phone: 919-515-2444 Fax: 919-515-7721 Email: lara_shields@ncsu.edu (alt. sps@ncsu.edu) North Carolina State University Sponsored Programs & Regulatory Compliance Services Campus Box 7514, 2701 Sullivan Drive, Suite 240 Raleigh, NC 27695-7514
12. **Reserved**	13. **NCSU Fiscal Officer:** Name: Ms. Julie Schwindt Phone: 919-515-8008 Fax: 919-515-4693 Email: julie_schwindt@ncsu.edu Address: North Carolina State University Office of Contracts & Grants Campus Box 7214 Raleigh, NC 27695-7214
14. **Remittance Address:**	15. **Send Invoices To:** Name: Dollie Moore Address: North Carolina State University CALS Business Office Campus Box 7644 Raleigh, NC 27695-7644

16. **Incorporation**: The documents checked are incorporated into this subaward as noted:

- ☒ NCSU Standard CR Subaward Terms and Conditions, 08-10, by reference, see. (http://research.ncsu.edu/sparcs/awards/subawards/)
- ☐ NCSU Standard FP Subaward Terms and Conditions, 08-10, by reference, see. (http://research.ncsu.edu/sparcs/awards/subawards/)
- ☒ Appendix A: SUBRECIPIENT's Proposal and or Statement of Work, including the approved budget, attached.
- ☒ Appendix B: Funding Source Prime Agreement, attached.
- ☐ Other:

17. Special Terms & Conditions from # 6, may be continued here:

NCSU
Terms and Conditions
Cost Reimbursement Subaward 08-10

1. **General Provisions.**

A. These terms and conditions apply to all Cost Reimbursement Subawards issued by NCSU. They are binding when incorporated by reference into a fully executed NCSU Subaward, using a Subaward Notice (SN). All references to "Block #" are to the SN. The SN identifies the parties, the key persons, the project proposal, establishes funding and cost share obligations, the period of performance, special terms and conditions, and carries the signatures of authorized representatives of each party.

B. The Subaward may also include other documents incorporated by the SN. Such other documents may include a proposal from the Subrecipient, or a Statement of Work with a budget as well as a Prime Award from the sponsor.

C. The Subaward is a binding agreement whereby the Subrecipient shall provide the personnel, materials, required facilities and use its reasonable best efforts to accomplish the work described in the project proposal (incorporated into this Subaward as Appendix A) or required by the associated Statement of Work. NCSU in turn agrees to reimburse Subrecipient for the allowable costs of said project or work effort in accordance with these and other incorporated terms, up to a total funded dollar amount, (Block 7).

D. The Subaward supersedes any prior or contemporaneous agreements or representations, between the parties regarding the proposed project, whether oral or written. Each party remains an independent entity. The Subaward does not establish any employment or agency relationship between the parties.

2. **Changes and Modifications**

A. These Terms and Conditions may be altered by the Special Terms and Conditions recorded on a given SN or in subsequent written modifications. Any changes to the Subaward after the initial SN has been executed must be recorded in written modifications, using the SN form annotated with a Modification Number. Both parties must sign modifications, except that NCSU may elect to issue the following types of modifications unilaterally:

1. Changes in key personnel when subrecipient submits a written request for change
2. Revisions to the project budget when subrecipient submits a written request
3. Changes to administrative information
4. Funding actions identified in the approved budget
5. Extension of the project end date (no-cost extension)

B. Subrecipient may reject such unilateral modifications by providing written notice of exceptions to the NCSU Negotiator /Administrator (Block #11) within 30 days after receipt of said modification. If the Subrecipient objects to a unilateral modification, the parties will negotiate an acceptable one.

3. **Incorporation of Prime**. The Subaward is also subject to the terms and conditions of the Prime Agreement, identified in Block #4 and incorporated into the Subaward as Appendix B. Prior approval from NCSU is required to extend the period of performance of this Subaward. Any exceptions or additions to the Prime Award will be identified in Special Terms and Conditions, Block #6. In the event of conflicts among the various documents and agreements, the following order of precedence will govern:

   1. Subaward Notice including any Special Terms and Conditions and modifications
   2. NCSU Standard Terms and Conditions Cost Reimbursement Subaward -08-10
   3. Proposal or Statement Of Work, and approved budget incorporated into the Subaward
   4. Terms and conditions of the Prime Award

4. **Invoice and Payment**.

   A. Subrecipient must request reimbursement for allowable costs incurred no more frequently than monthly but at least quarterly from the individual named in Block #15. Invoices must include the Subaward number; the period covered by the invoice and must show the same level of cost detail as the approved proposal budget. Invoices must show expenditures and cost share contributions for the current period and the cumulative amount to date. The invoice must include a certification by an authorized official as to truth and accuracy of the invoice.

   B. Subrecipient must submit an invoice marked "FINAL," not later than forty-five (45) days after Subaward end date. Notwithstanding any terms and conditions or other provisions contained in the final invoice or any accompanying correspondence, the final invoice and/or financial statement constitutes Subrecipient's final request for reimbursement and upon its payment by NCSU, a release by which the Subrecipient does remise, release and discharge NCSU, its officers, agents and employees of and from all liabilities, obligations, claims and demands whatsoever under or arising from the Subaward. Both NCSU and Subrecipient understand that all payments are provisional and are subject to adjustment as a result of an adverse audit finding concerning the Subaward. In the event that Subrecipient fails to submit either a FINAL invoice or request for no-cost extension within the time frame established above, NCSU shall consider the last regular invoice to be the FINAL invoice. Any unexpended balance from the Total Sponsored Funds to Date (7.d.) will be automatically deobligated and NCSU will not make any further payments to that Subrecipient.

   C. If a cost-sharing amount appears in Block #7e, Subrecipient must report such cost-share expenditures to NCSU with each invoice, either on the invoice or separately on the Subrecipient's letterhead. The report must show current period expenditures, cumulative expenditures, and a certification as to the truth and accuracy of the report. The Subrecipient may not use Federal funds to meet cost-share obligations under any other Federal awards.

5. **Books and Records**. The Subrecipient will make all financial records, supporting documents, correspondence and any other records applicable to the Subaward available at all reasonable times for inspection, review and audit by the Prime Sponsor, by NCSU or by their authorized representative(s). Subrecipient must retain these records for a period of at least three (3) years from the date of final invoice or from the settlement date of any claims, audits, appeals, or litigation, whichever is later, or as the Prime Agreement prescribes.

6. **Audit**. Throughout the term of the Subaward, Subrecipient agrees to forward upon request, audit information in accordance with OMB Circular A-133. This could include certification of audit results, web links to audit reports, the most recent report, corrective action plans or other pertinent information. In the absence of an A-133 audit, Subrecipient must submit a record of its most recent audit by an independent accountant, including a certification as to the accuracy and reliability of the Subrecipient's financial statements and internal control structure. Upon request, Subrecipient must complete a questionnaire (to be provided) regarding its accounting system and internal controls. Audits and/or related documents must be sent to the address in Block 13, Attn: Compliance Manager.

7. **Key Persons, Technical Direction and Reporting**.

   A. The individual named in Block #8 (normally Subrecipient's Principal Investigator) is designated as a Key Person. Subrecipient agrees not to replace that individual nor reduce his/her level of commitment to the project without prior written approval of NCSU.

   B. The NCSU Project Director named in Block #9 is responsible for monitoring Subrecipient's performance, technical reporting and approval of Subrecipient's invoices. All questions about technical and financial matters should be directed to that individual. Technical reporting requirements are stated in Block #6.

8. **Administration**. Matters concerning any changes in the terms, conditions, dates or amounts cited in the SN should be directed to the other party's Negotiator /Administrator identified in Blocks #10 and #11.

9 **Publications**. Subrecipient and its investigators are free to publish papers dealing with the results of the research project sponsored under this Subaward. However, Subrecipient must give NCSU's Project Director (Block #9) the opportunity to review such papers or presentations prior to their being released. NCSU agrees to complete such review within sixty (60) days. Subrecipient must include in every publication or presentation appropriate recognition of the support received from NCSU and the Prime Sponsor.

10. **Certifications and Assurances**. Subrecipient, by signing the SN incorporating these Terms and Conditions, certifies its compliance with any applicable regulatory requirements including but not limited to those listed below. Subrecipient agrees to immediately report to NCSU any change in its compliance status. Subrecipient must flow these requirements down to any lower tier subrecipients. See Appendix B of the Federal Demonstration Partnership Operating Procedures

(http://www.nsf.gov/awards/managing/fed_dem_part.jsp.) for a complete description of the following:

1. Nondiscrimination statues on the basis of race, color, national origin, sex, blindness, handicap or age.
2. Common Federal Policy for the Protection of Human Subjects (45 CFR Parts 46 & 690).
3. USDA Rules that implement the Laboratory Animal Welfare Act of 1966 (9 CFR Parts 1-4).
4. Regulations for the Clean Air Act, 42 USC 7606, 40 CFR 6 & 32.
5. Regulations for the Clean Water Act 33 USC 1368, as implemented by E.O. 11738.
6. National Scenic Rivers Act of 1968, 16 USC1271, 40 CFR 6.
7. For NSF & DHHS awards only, internal conflict of interest policy.
8. E.O. 11246, & E.O. 11375 "Equal Employment Opportunity," per 41 CFR part 60.
9. OMB Circular A-129 and 40 CFR 30.73, the parties are not delinquent on any Federal debt.
10. The parties are in compliance with the Drug-Free Workplace Act of 1988, Public Law 100-690, 41 USC 701, 40 CFR 32 or equivalent.
11. HIPPA Patient Privacy Rule, 45 CFR 160 & 164.
12. Coastal Barriers Resource Act, 40 CFR 6.
13. The Anti-Kickback Act of 1986, Pub. L. 99-634, amending 18 U.S.C. 874, 29 C.F.R. Part 3
14. The Safe Drinking Water Act, 42 U.S.C. 300h-3(e)
15. Davis-Bacon Act, 40 U.S.C. 276a to 276a-7, 29 C.F.R. Part 5
16. Contract Work Hours and Safety Standards Act, 40 U.S.C. 327 – 330, 29 C.F.R. Part 5
17. Environmental Protection Agency Regulations, 40 C.F.R. Parts 1 through 49
18. Mandatory Standards & Policies contained in the State Energy Conservation Plan issued in compliance with the Energy Policy and Conservation Act, Pub. L. 94-163, 89 Stat. 871
19. "Debarment and Suspension" Regulations under E.O. 12549 & 12689, 7 CFR 3017, 10 CFR 606 & 40 CFR 32, or equivalent.
20. Prohibitions against lobbying as set forth in 7 CFR 3018, 31 USC 1352 and 18 USC 1913.
21. The Hatch Act (5 U.S.C. s 1501-1508 and 7324-7328) which limits the political activities of employees whose principal employment activities in whole or in part supported by Federal Funds.
22. Comply with environmental regulations that may be issued pursuant to:
    a. Institution of environmental quality control measures under NEPA (PL 91-190 & EO11514.
    b. Notification of violating facilities EO 11738
    c. Protection of wetlands EO 11990
    d. Evaluation of flood hazards in floodplains EO 11988
    e. Assure project consistency under Costal Zone Management Act of 1972 16 USC 1451
    f. Endangered Species Act of 1973, as amended PL 93-205
    g. National Historic Preservation Act of 1966, 16 USC470, EO11593
    h. Lead-Based Paint Poisoning Prevention Act 42 USC 4801
    i. Requirements governing the applicable Grant Program

(Abbreviations: CFR = "Code of Federal Regulations," USC = "United States Code," E.O. = "Executive Order," OMB = "Office of Management and Budget")

11. **Termination**.

A. NCSU and Subrecipient have the right to terminate the Subaward in whole or in part, without cause, with 30 days advance written notice to the other party.

B. The Subrecipient must stop work to the extent specified in the Notice of Termination on the date such notice is received from or issued to NCSU. Subrecipient may not place any orders or subcontracts for materials, services, or facilities, except as may be necessary for the completion of such portion of the work that is not terminated. NCSU agrees to reimburse the Subrecipient for all allowable costs of the work that has been performed prior to said notice of termination and all obligations relating to such work that cannot be canceled.

12. **Liability**. Each party is responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by applicable law.

13. **Notices**. Unless otherwise provided in the SN, official notices, from either party to the other, shall be deemed to have been fully given when made in writing, addressed/delivered to the individual shown on the SN, Block #10 for Subrecipient and Block #11 for NCSU. The parties agree that the following methods are acceptable for delivering official notices: Certified mail, return receipt requested, electronic mail with confirmation of receipt, Express courier service (e.g. FedEx or UPS) or fax with confirmation of receipt.

14. **Assignment and Subcontracting**. Subrecipient may not assign the Subaward nor any right, remedy, obligation or liability arising there under or by reason thereof nor may Subrecipient further subcontract any of the work to be performed under the Subaward without prior written approval from NCSU.

15. **Inspection**. Designated representatives of NCSU have the right to inspect and review the progress of the work performed at the Subrecipient's place of business pursuant to this Agreement. Subrecipient must make available all reasonable facilities, including access to relevant data, test results, and computations used or generated under this Agreement if requested by NCSU. NCSU must conduct such inspections in such manner so as not to unduly delay the progress of the work. NCSU must give the Subrecipient reasonable notice prior to conducting any such inspection.

16. **Use of Names**. Either party may use the name of the other in a public announcement of the existence of the Subaward. Other than that, neither party to the Agreement may use the names, marks or symbols of the other or of the other party's employees in any manner, including public announcements, advertising, or promotional sales literature without the prior written consent of the other party.

17. **Disputes**. In the event of a dispute or claim regarding any matter under the Subaward that is not disposed of by mutual agreement, the parties agree to pursue those necessary institutional and/or legal remedies as may be appropriate. Legal remedies may include pursuit of the dispute by either party in a court of competent jurisdiction. In this event, each party shall be responsible for all costs they incur as a result of such action. Subrecipient agrees to continue performance on a disputed matter until any such dispute is resolved.

18. **Inventions**.

A. The parties agree to abide by the applicable United States regulations governing patents and inventions issued by the US Department of Commerce at 37 CFR 401, wherein the rights of the Federal Government are established. Any invention or discovery made or conceived in the performance of the research or other work (hereinafter called "Invention"), or any patent to be granted on such Invention shall be jointly or individually owned by Subrecipient and/or NCSU in accordance with the following criteria:

1) Title to any Invention made or conceived jointly by employees of both Subrecipient and NCSU in the performance of the Research (hereinafter called "Joint Invention") shall vest jointly in NCSU and Subrecipient.

2) Title to any Invention made or conceived solely by employees of either Subrecipient or NCSU in the performance of the Research shall vest in the party whose employees or students made or conceived such Invention or discovery.

B. The Subrecipient will, within 2 months after their inventor makes a written disclosure, submit a written report to the NCSU Administrator (Block 11), identifying the Subaward number, date of disclosure by Subrecipient's PI, and a brief (non-disclosing) description, identifying the purpose of the invention. Subrecipient will concurrently make a full disclosure directly to the Prime Sponsor in accordance with the Prime Agreement.

C. The Subrecipient will submit a final invention report to NCSU concurrently with the final invoice. Subrecipient will use the forms prescribed by the Prime Sponsor (e.g. DD Form 882 or NASA Form C-3044). The list will identify all subject inventions, including the disclosure date(s) or stating that there were no inventions (negative report is required).

D. The Subrecipient will, upon request, submit a written report concerning each patent filing, including: the filing date, serial number and title, a copy of the patent application, patent number, and issue date.

19. **Copyright**. The Subrecipient may copyright any work product, software or data that is subject to copyright and was first developed by or on behalf of Subrecipient under the Subaward. For such copyrights or copyrighted material (including any computer software and its documentation and/or databases), subject to its legal ability to do so, Subrecipient grants to the Federal Government the rights established in the Prime Agreement and grants to NCSU, an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, display, and perform publicly to the extent required to meet NCSU's obligations under its Prime Agreement and for the purposes of its noncommercial research and educational missions.

20. **Data Rights** For Data and computer software created in the performance of this Subaward Agreement, Subrecipient grants to the Prime Sponsor the rights established in the Prime Agreement and grants to NCSU the right to use data to the extent required to meet NCSU's obligations under its Prime Agreement and for the purposes of its noncommercial research and educational missions.

21. **Confidentiality**

A. In the performance of the Project, it may be necessary for one party to disclose information that is proprietary and confidential to the disclosing party. All such information must be disclosed in writing and designated as confidential or, if disclosed orally, must be identified as confidential at the time of disclosure and confirmed in writing and designated as confidential within thirty (30) days of such disclosure. Except as otherwise provided herein, for a period of Three (3) years following the date of such disclosure, the receiving party agrees to use the confidential information only for purposes of this Agreement and further agrees that it will not disclose or publish such information except that these restrictions do not apply to:

(i) information that is or becomes publicly known through no fault of the receiving party;

(ii) information learned from a third party entitled to disclose it;

(iii) information already known to or developed by receiving party before receipt from disclosing party, as shown by receiving party's prior written records;

(iv) information for which receiving party obtains the disclosing party's prior written permission to publish;

(v) information required to be disclosed by court order or operation of law, including, but not limited to, the North Carolina Public Records Law; or

(vi) information that is independently developed by the receiving party's personnel who are not privy to the disclosing party's confidential information.

B The receiving party must use a reasonable degree of care to prevent the inadvertent, accidental, unauthorized or mistaken disclosure or use by its employees of confidential information disclosed hereunder.

22. **Law and Severability**. It is agreed that if either party is an agency of its respective state government, the applicable constitutional provisions or statutes that govern sovereign immunity shall dictate the appropriate forum and law governing substantive issues. Subrecipient agrees to comply with all relevant federal, state, county, and municipal executive orders, rules, regulations, laws and ordinances. In the event that any provision(s) of the Agreement are rendered void or illegal the remainder of its provisions shall remain in effect. Failure on the part of either party to exercise a right or remedy shall not preclude exercising them in the future.

23. **Survivability** In the event of early termination of this Subaward, the parties agree that Articles 18 through 21 and the obligations inherent in them will survive the termination of this agreement for a minimum of 3 years.

24. **Export Controls**. The parties acknowledge that each is responsible for compliance with US Export Control regulations. In the event that either party becomes aware that the research work that is being or will be conducted, is or is likely to involve a technology that is subject to Export Controls, each party agrees to notify the other within three working days so that the situation can be evaluated and an appropriate course of action taken.

End of NCSU Terms and Conditions Cost Reimbursement Subaward

Appendix A

Training and Dissemination of Outreach Information to Molluscan Shellfish Stakeholder Groups about Virus Contamination and Disease Risks

Investigator & Affiliation:
Ken Moore (Principal Investigator)
Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223-1740
Phone: 803-788-7559
Fax: 803-788-7576
Email: issc@issc.org

Purpose and Objectives (Including Statement of Deliverable):

Today, human noroviruses are the leading cause of foodborne illness risks for United States consumers (Scallan, 2011). Most foodborne outbreaks of viral gastroenteritis continue to be associated with the food service industry, with contamination occurring during food preparation, and outbreaks are most often associated with complex foods consisting of more than a single commodity ingredient. When a simple food consisting of only a single commodity is responsible for a disease outbreak, data from 2001 to 2008 shows that molluscan shellfish ranked #3 in importance (Hall, 2012). Molluscan shellfish are unique from more complex foods in that they generally are contaminated in the pre-harvest environment (due to human fecal contamination in harvesting waters); as filter-feeders, they concentrate viruses from the water column resulting in high levels of contamination in the shellfish meat; and they are consumed whole and raw or only partially cooked.

Sporadic outbreaks of norovirus caused by molluscan shellfish continue to occur in the United States despite extensive measures by Federal and State regulatory agencies to implement shellfish sanitation programs in all "harvest states." These programs rely on shoreline surveys along with water testing of shellfish growing waters to predict the suitability of sites for shellfish harvesting. Growing waters are tested for microbial indicator organisms that have proven valuable for predicting the sanitary quality of water with respect to fecal contamination. However, there are no accurate, robust, and cost-effective methods for analyzing shellfish growing waters or shellfish themselves directly for the pathogens responsible for causing human illnesses. The current techniques utilized by state shellfish sanitation programs are generally effective as evidenced by only the sporadic occurrence of recalls and illnesses associated with molluscan shellfish today. The thought is that when disease outbreaks occur, they are directly related to a single focal contamination event, as opposed to continual contamination, such as by non-point source pollution (e.g., inefficient municipal waste treatment or failing on-site waste treatment systems).

Because of this, the focus of an outreach and educational program should be **PREVENTION** of focal contamination events in close proximity to the shellfish growing waters. Likewise, the target audience of such an educational program should be those that may cause such an event, either accidentally or intentionally. The groups potentially responsible for such events are those who use the waters, either for commercial fishing or recreationally.

The Interstate Shellfish Sanitation Conference (ISSC) holds a Biennial Meeting where Federal regulatory groups come together with state regulatory groups and with the shellfish industry to discuss and promote shellfish sanitation for the United States. At the 2011 Biennial Meeting, a mandatory harvester and dealer continuing education requirement was approved for licensure of harvester and dealers in all relevant states. That requirement was enacted on January 1, 2014, and those states without a continuing education program are currently out of compliance with the National Shellfish Sanitation Program (NSSP) guidelines. To date, several of the states have developed their own stand-alone programs, but in general, most states have not developed a program and only a handful are at the stage of implementing a program to meet this requirement. The ISSC has worked with the University of Florida to develop an online training course that will meet the NSSP guidelines for this training (using Articulate Storyline software). The training course was originally developed for the State of Florida and as such, had state-specific information within the training curriculum. The ISSC has worked with the University of Florida to remove most of the state-specific information and have subsequently provided this as a template to the ISSC for distribution to other states for their use in developing programs that will meet the harvester and dealer training program requirements. However, many of the states are not in a position to purchase this software or have personnel that are trained in using the software to manipulate the templates such that they can develop a program that is applicable to their state.

The templates, as currently designed, have a great deal of valuable information in them related to shellfish harvesting and handling, along with information about microbial, chemical, and other contaminants. Overall the focus on microbial contaminants is for bacteria; although, there is a small amount of information related to viral contamination of shellfish growing waters. Because these templates will be the basis of a national training program program required by NSSP guidelines, the intention will be to update the information in the templates and include information about risks associated with viral contamination of molluscan shellfish, with the emphasis on PREVENTING contamination of shellfish growing waters. This program and the information therein will be used across the country and will target commercial shellfish industry personnel (harvesters and dealers).

The other target audiences that can potentially impact shellfish growing waters are recreational boaters and fishermen. It is unclear at this point how to mount the most effective and cost-efficient outreach and educational campaign for these groups. Because the ISSC has connections with the states, they are in a prime position to develop and conduct a survey to gather information about avenues for reaching these audiences.

So, it is clear that viral contamination of molluscan shellfish in the United States can pose risks to consumers and that the major route of contamination occurs from focal incidents occurring in the pre-harvest growing waters. An effective outreach and educational campaign will focus on target audiences that may adversely impact growing waters, such as the commercial fishing industry as well as recreational boaters and fishermen. The opportunity exists to develop educational information that will specifically target the commercial industry through NSSP-mandated training requirements for shellfish harvest and dealer licensure. More information is needed on how to mount an effective campaign to reach recreational boaters and fishermen. With this in mind, the objectives of the proposed project are listed below.

Objectives:

There are five primary objectives for this proposed project, which are to:

1. obtain and provide the necessary computer software to "harvesting states", enabling them to modify existing ISSC Harvester and Dealer Training Program templates and design training materials to meet the NSSP requirements for shellfish harvester and dealer training;
2. provide technical support and assistance to "harvesting states" as necessary, for them to design and update the ISSC Harvester and Dealer Training Program templates with their state-specific information;
3. update the existing ISSC educational DVD that focuses on overboard waste dumping and pump stations, by adding virus-related content for outreach to molluscan shellfish stakeholder groups;
4. sponsor a national conference hosted by the ISSC to share information about viral illnesses associated with molluscan shellfish and novel alternate indicators that may be used for managing shellfish growing and harvest waters; and
5. develop and conduct a survey to "harvesting states" to assess how best to disseminate educational information to recreational boaters about microbial contamination of molluscan shellfish growing and harvest waters.

The overall goal for this proposed work is to establish a multi-tiered approach for disseminating information about viral- and other microbial-related risks to a wide range of molluscan shellfish stakeholder groups. The groups targeted for this outreach and education will include the shellfish industry (harvester and dealers) as well as recreational boaters and fishermen. These goals will be accomplished by providing the necessary software and technical assistance to "harvesting states" for them to develop state-specific training materials to meet the new NSSP shellfish harvester and dealer program training requirement; by updating the ISSC DVD that focuses on overboard waste dumping and pump stations through the addition of content addressing waste impacts to growing waters; and by developing, administering, and analyzing data from a state survey to determine the most effective method for disseminating information to recreational boaters and fishermen. For each of these national efforts, specific information will be included in the training modules to outline how shellfish growing waters are contaminated with microbial pathogens; their public health significance; the message that prevention is the best control; and a description of specific prevention strategies than can practically be implemented by each stakeholder group. The intent is to both promote public health while being good stewards of the environment and still supporting and promoting the commercial fishing industry.

Justification:

Given that molluscan shellfish are a major food commodity associated with viral gastroenteritis, in February, 2014, the NoroCORE team convened a Shellfish Outreach Advisory Panel to determine the most cost-effective and efficient ways to disseminate information about prevention of viral illness and reduction of risks associated with consumption of molluscan shellfish. This panel had representatives from the Interstate Shellfish Sanitation Conference (ISSC), the Food and Drug Administration – Center for Food Safety and Applied Nutrition (FDA-CFSAN), the US Department of Agriculture – Agricultural Research Service (USDA-ARS), the National Oceanic and Atmospheric Administration, National Sea Grant program (NOAA, Sea Grant), as well as from the North Carolina Department of Environment and Natural Resources Commission, Shellfish Sanitation and Recreational Water Quality group (NC DENR). The consensus of the group is that current methods for mitigating consumer risks in shellfish following their contamination in growing waters are unproven, unreliable, and unrealistic at this time. Furthermore, **PREVENTION** of microbial contamination in shellfish harvest waters should be the focus of an outreach and education program for reducing consumer risks associated with viral contamination of molluscan shellfish. The group further went on to say that significant microbial contamination of molluscan

shellfish occurs as the result of focal contamination events (i.e. catastrophic municipal failures, illicit overboard discharges, accidental overboard discharges of fecal matter or vomitus, etc.), so educational efforts should be targeted at those groups that may be responsible for these types of contamination events (shellfish harvester and dealers, recreational boaters and fishermen, etc.) and strategies should center on **PREVENTION** of these events. The advisory panel agreed that education is the key focal point, noting that there is flexibility in how the educational material is developed and that there are substantial challenges related to these particular audiences (potentially, lack of education, lack of buy-in, and language barriers). The conclusions were to utilize a multi-tiered approach for reaching these diverse audiences by building upon existing ISSC-sponsored initiatives, including the NSSP mandatory harvester and dealer training requirements.

Methods:

The ISSC will administer and oversee proposed project activities. Initially, the ISSC will coordinate with states to determine which have access to appropriate software (Articulate Storyline) for developing online continuing education for the shellfish industry, primarily for molluscan shellfish harvester and dealers. The ISSC will then purchase copies of the software and distribute them to a subset of the corresponding key "harvest states" such that state personnel can develop a program specifically meeting their state information and requirements. Such a program will also consider the unique needs for their industry while still meeting the NSSP mandated requirements for harvester and dealer training.

In addition to the purchase of appropriate software, the ISSC will retain the services of an Articulate Storyline programmer that is knowledgeable about the use of the software program. This programmer will be available to "harvest states" to assist as they develop state-specific information suitable to meet the NSSPmandated training requirements for shellfish harvesters and dealers. Additionally, the ISSC will work with the programmer to develop a database or collection of appropriate photos and other visual aids to be used for developing state programs from the ISSC templates currently available. This database will be housed at the ISSC headquarters and will be made available to states for their use (along with all copyrighted information clear for free distribution). Finally, the programmer will work with the ISSC to extract excerpts from the current ISSC DVD that focuses on waste discharges and pump stations from boats. This information will be inserted and used in the ISSC Storyline templates.

In addition to these activities, the ISSC will work to collect new video footage that can be used to update their current DVD which focuses on overboard waste discharges and the proper use of dump stations for containment and disposal of fecal wastes. The ISSC will work with a video editor to update this video and any accompanying visual materials (i.e. brochures), including information about viral- and other microbial pathogenic organisms.

Because questions exist around the use of current bacterial indicators for predicting the microbial quality of molluscan shellfish growing and harvest waters with respect to human viruses, research in recent years has focused on identifying novel, robust, and economical alternate indicators that may better predict fecal contamination resulting in foodborne illnesses for shellfish consumers. While many in the field are aware of the previous and ongoing studies, to date, there has not been an appropriate venue to disseminate information and for invited experts to discuss the relevance of new findings for improving the management of shellfish growing and harvest waters. To address this, the ISSC will sponsor a conference to discuss the importance of PREVENTING human fecal contamination in

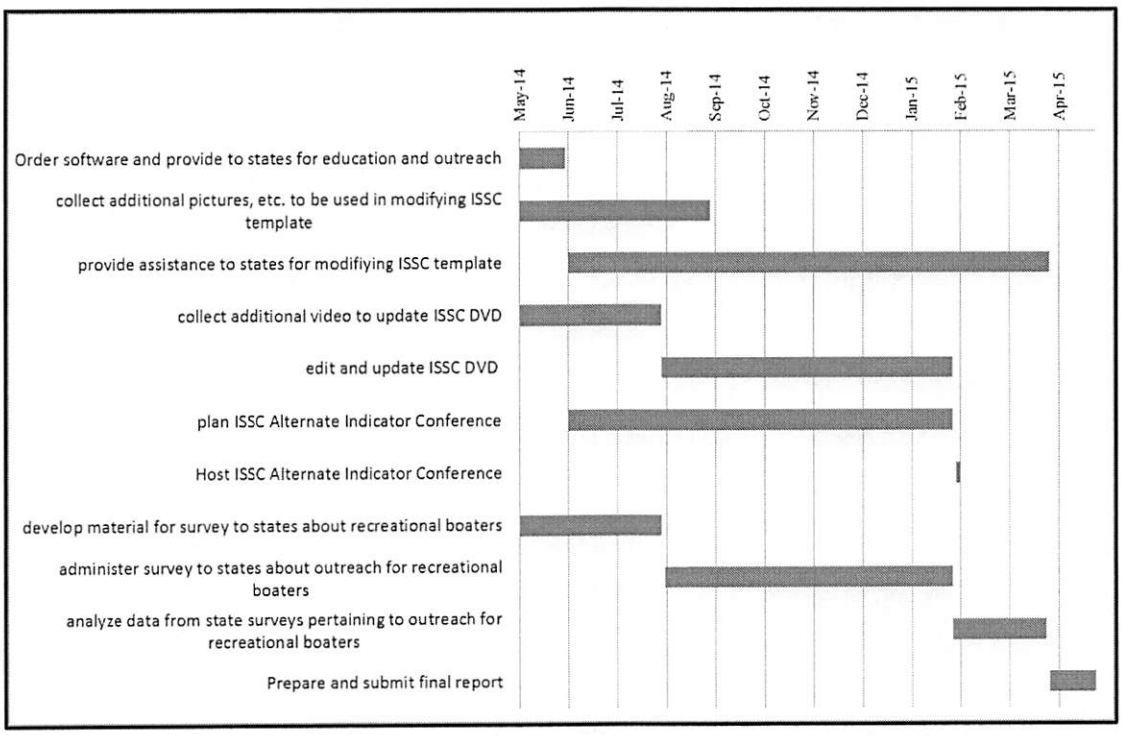
environmental waters and to provide a venue for discussing the utility of alternative microbial indicators in the future to better manage molluscan shellfish growing and harvest waters.

Finally, the ISSC will develop a survey (either hardcopy for distribution or through using Articulate Storyline) using standard survey techniques that will be distributed to State Shellfish Control Authorities in "harvest states" for their feedback about the impacts that recreational boaters and fishermen may have on shellfish growing waters. The survey will include questions about the number and percentages of waste dump stations that are available in their state as well as questions about the most effective and cost-efficient methods that can be used to reach recreational boaters and fishermen. The ISSC will develop and conduct this survey over an approximately six month window, then compile and analyze the information for inclusion in the final project report to NoroCORE. Examples of survey questions include (but are not limited to):

1. Do recreational fishermen and boaters impact shellfish growing waters within your state?
2. Do most recreational fishermen and boaters within your state understand the importance of containing fecal material and vomitus using an approved storage container on their boat?
3. How many marinas in your state have waste dump stations (total number and percentage)?
4. Is there State or Federal funding available within your state to assist marinas with dump stations (building and maintenance)?
5. What might be the most appropriate method for distributing educational materials to recreational fishermen and boaters within your state?
6. Would "barf bags" with educational materials about fecal material and vomitus impacts to the environment (shellfish growing waters) be one appropriate tool for distributing information?

The proposed work is a multi-tiered approach for reaching different audiences that potentially contribute to microbiological (viral) contamination of shellfish growing waters. With this proposed work, viral- and other microbial contamination information will be updated in the NSSP program for training of industry personnel (shellfish harvesters and dealers) that will be used in many "harvest states" across the United States. In addition to reaching industry personnel, this proposed approach will collect information from states about the impacts that recreational fishermen and boaters may have on shellfish growing waters and avenues that may be most effective in reaching these target audiences. The ISSC will prepare a final report to document these activities as well as to summarize the findings from the state survey regarding recreational fishermen and boaters. This approach should result in an effective education and outreach program for delivering information about viral- and other microbial contamination of shellfish growing waters that should lead to more effective PREVENTION of contamination events.

Time Table: (1 yr; proposed start date of 5/1/14)



Budget: Total of $99,999 is requested (direct cost $86,956 indirect cost $13,043)

Salary	Costs
A. Ken Moore (6%; $108,435)	$6,500
B. Storyline technician (400 hrs; $25/hr)	$10,000
C. Survey Developer/Analyst (400 hrs; $30/hr)	$12,000
D. Admin Support (5%; $50,000)	$2,500
E. Admin Assistant (30.7%;$30,000)	$9,500
Travel	
consult on Storyline development	$3,000
administer state survey materials	$6,000
collect video for updating ISSC DVD	$5,000
travel for ISSC conference participants	$10,000
Materials and Supplies	
software	$15,000
software training manual development	$1,956
DVD updates	$4,000
survey materials	$1,500
Total Direct Costs	$86,956
Indirect Costs (**15%** of Total Direct Costs)	$13,043
TOTAL PROJECT COSTS	**$99,999**

Budget Justification:

Salary: Project funds ($6,500) are requested to support Ken Moore, project PI. Ken will dedicated 6% of his time and effort to this project (6%; yearly salary = $108,435). Funds are also requested for an hourly technician that is familiar with the Storyline software (400 hours; $25/hour; total = $10,000) and for an hourly survey developer/analyst that can develop and analyze data collected through the state survey to assess outreach for recreational boaters (400 hours; $30/hour; total = $12,000). In addition, funds are requested for secretarial/administrative support (31.7%; $30,000; total = $9,500) and a data analyst (5%; $50,000; total = $2,500) that will provide Storyline technical assistance as well as to assist in analyzing survey results.

Travel: All travel is domestic. Project funds are requested for travel to "harvest states" for consultation with the Storyline developer as they assist each state with development of a program specific for use in training their harvesters and dealers ($3,000). Funds are also requested to travel to states as the survey materials are administered to assess outreach for recreational boaters ($6,000). Travel funds are also requested to visit specific harvesting state locations for collecting video that will be used to update the current ISSC DVD aimed at overboard discharge and the use of pump stations, as well as to collect pictures that will be archived in the ISSC database for use in developing state-specific harvester and dealer training programs ($5,000). Finally, the ISSC will host a conference to discuss human enteric virus impacts to shellfish growing waters and the use of alternative indicators for management of shellfish growing and harvest waters. Funds ($10,000) are requested to assist with venue costs for this conference and to assist with travel for state personnel and appropriate experts for the meeting.

Materials and Supplies: Project funds ($15,000) are requested for the purchase Storyline software that will be distributed to 10-15 harvest states for developing their state-specific harvester and dealer outreach program. In tandem, project funds are requested to print appropriate materials for a software training manual that can be distributed to the states to assist them with learning to use the Storyline software ($1,956). Finally, project funds are requested for small equipment (cameras, associated software) to obtain visuals/video for updating the existing ISSC DVD ($4,000) and for printing and distribution associated with administering the recreational boater survey to the states ($1,500).

In total, this project requests $86,956 in direct costs to meet the outline project objectives. The ISSC requires a 15% administrative overhead for operational costs associated with the project ($13,043). Therefore, the total project costs requested are for $99,999.

References:

Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. 2011. Foodborne illness acquired in the United States—major pathogens. Emerg Infect Dis. 17:7–15.

Hall AJ, Eisenbart VG, Etingue AL, Gould LH, Lopman BA, Parashar UD. 2012. Epidemiology of foodborne norovirus outbreaks, United States, 2001–2008. Emerg. Infect. Dis. 18:1566–1573.

KENNETH B. MOORE

Education

M.A. 1987. Business Administration, Webster University, St. Louis, Missouri.
M.A. 1987. Public Administration, Webster University, St. Louis, Missouri.
B.S. 1976. Biology, Francis Marion University, Florence, South Carolina.

Professional Experience

1993 – Present Executive Director, Interstate Shellfish Sanitation Conference, Columbia, SC.

The Interstate Shellfish Sanitation Conference is a public health organization which fosters and promotes shellfish sanitation through the cooperation of state and federal control agencies, the shellfish industry, and the academic community.

2007 – 2010 Legislative and External Liaison, SC Department of Health and Environmental Control, Columbia, SC.

Served as assistant to the Deputy Commissioner of Health Regulations which provides oversight in regulations for health care facilities in the State of South Carolina.

1983 – 1993 Manager, Water Quality and Shellfish Sanitation Division, SC Department of Health and Environmental Control, Columbia, SC.

Managed the statewide shellfish sanitation program and the State Law Enforcement Unit. Reviewed field activities such as sanitary survey reports for growing area classification, received certification for all shellfish processing facilities and developed annual plan to ensure compliance with NSSP guidelines.

Recognition for Accomplishments

- Chairman, ISSC Executive Board, Columbia, SC. 1993 -1989
- Cooperative State Research and Education Extension Award for Leadership in HACCP. June 1999
- USDA Group Honor Award for Leadership in HACCP. June 1999

Professional Organizations

PAC-RIM Shellfish Association
Interstate Shellfish Sanitation Conference
National Shellfisheries Association
Northeast Shellfish Sanitation Association
Gulf and South Atlantic Shellfish Association
Interstate Shellfish Seminar
Gulf of Mexico Public Health Focus Team
National HACCP Alliance Group
Presidential Task Force on Marine and Freshwater Toxins

Presentations

- Yearly ISSC Update Report to regional shellfish associations.
- Yearly congressional update to members of Congress
- FDA Training Seminars
- Quarterly Gulf of Mexico Public Health Forums
- EPA Harmonization Water Quality Monitoring Requirements – Gulf Regional Workshop

ISSC

Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223-1740

Title	FDA/ISSC Cooperative Agreement Shellfish Safety Assistance Project*	FDA Small Scientific Conference Grant Program**
Principal Investigator	Ken B. Moore	Ken B. Moore
Amount	$ 325,000.00	$25,000.00
Start Date	September 1, 2013	September 1, 2013
End Date	August 31, 2014	August 31, 2014
Percent Time & Effort	90%	n/a*

* This is a five-year non-competing grant which renews annually until August 31, 2016.

**This grant provides travel assistance funding to State regulatory members to attend the ISSC Biennial Meeting. Administrative support is provided by the ISSC Program Manager which is approved by the Principal Investigator.

Phone 803-788-7559 Email issc@issc.org Fax 803-788-7576

ISSC

Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223-1740

May 9, 2014

Dr. Lee-Ann Jaykus, Ph.D.
William Neal Reynolds Distinguished Professor
Scientific Director, USDA-NIFA Food Virology Collaborative (NoroCORE)
Department of Food, Bioprocessing and Nutrition Sciences
North Carolina State University
Raleigh, NC 27695-7624

Dear Dr. Jaykus:

RE: Training and Dissemination of Outreach Information to Molluscan Shellfish Stakeholder Groups about Virus Contamination and Disease Risks
Principal Investigator: Kenneth B. Moore

The Interstate Shellfish Sanitation Conference (ISSC) is pleased to participate in the above referenced grant application as a subcontractor. We are aware of the necessary subcontract agreement which will be required consistent with policy of the granting agency and are prepared to enter such agreement.

We propose that the subcontractor work be authorized by either a grant or cost-reimbursable type contract drawn in the name of Interstate Shellfish Sanitation Conference. The contract agreement should include provisions acceptable to a non-profit 501(C) (3) organization and if possible we would prefer to be invoiced on a monthly basis. Please send any correspondence to:

Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223-1740

We are excited about the opportunity to work with your institution on this grant and look forward to hearing from you soon. Please contact us if additional information is needed.

Sincerely,

Ken B. Moore

Ken B. Moore
Executive Director

/nsd

Phone 803-788-7559 Email issc@issc.org Fax 803-788-7576

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0420921220000

*** Budget Type:** ☐ Project ☒ Subaward/Consortium

Enter name of Organization: Interstate Shellfish Sanitati

*** Start Date:** 06/01/2014 *** End Date:** 05/31/2015 **Budget Period** 1

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Mr.	Ken		Moore		PI		0.72			13,012.00	0.00	13,012.00
2.													
3.													
4.													
5.													
6.													
7.													
8.													

9. **Total Funds requested for all Senior Key Persons in the attached file**

Total Senior/Key Person 13,012.00

Additional Senior Key Persons: Add Attachment | Delete Attachment | View Attachment

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Storyline Technician				20,000.00	0.00	20,000.00
1	Survey Developer				12,000.00	0.00	12,000.00
1	Data Analyst	1.20			8,333.00	0.00	8,333.00
3	**Total Number Other Personnel**					**Total Other Personnel**	40,333.00

Total Salary, Wages and Fringe Benefits (A+B) 53,345.00

OMB Number: 4040-0001
Expiration Date: 04/30/2008

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS: 042092122000

* Budget Type: ☐ Project ☒ Subaward/Consortium

Enter name of Organization: Interstate Shellfish Sanitatio

* Start Date: 06/01/2014 * End Date: 05/31/2015 Budget Period 1

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

	Equipment Item	* Funds Requested ($)
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.	Total funds requested for all equipment listed in the attached file	
	Total Equipment	

Additional Equipment: Add Attachment | Delete Attachment | View Attachment

D. Travel

		Funds Requested ($)
1.	Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	24,000.00
2.	Foreign Travel Costs	
	Total Travel Cost	24,000.00

E. Participant/Trainee Support Costs

		Funds Requested ($)
1.	Tuition/Fees/Health Insurance	
2.	Stipends	
3.	Travel	
4.	Subsistence	
5.	Other	
	Number of Participants/Trainees	Total Participant/Trainee Support Costs

OMB Number: 4040-0001

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Expiration Date: 04/30/2008

RESEARCH & RELATED BUDGET - SECTION F-K, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS: 042092120000

* Budget Type: ☐ Project ☒ Subaward/Consortium

Enter name of Organization: Interstate Shellfish Sanitatior

* Start Date: 06/01/2014 * End Date: 05/31/2015 Budget Period 1

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Software (Storyline)	16,500.00
9. Printing	4,000.00
10. Small equiment and CVs for video	5,500.00
Total Other Direct Costs	26,000.00

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	103,345.00

H. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1.				
2.				
3.				
4.				
	Total Indirect Costs			

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	103,345.00

J. Fee	Funds Requested ($)

K. * Budget Justification: ISSC Budget Justification FINAL REVISI [Add Attachment] [Delete Attachment] [View Attachment]

(Only attach one file.)

OMB Number: 4040-0001
Expiration Date: 04/30/2008

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - Cumulative Budget

		Totals ($)
Section A, Senior/Key Person		13,012.00
Section B, Other Personnel		40,333.00
Total Number Other Personnel	3	
Total Salary, Wages and Fringe Benefits (A+B)		53,345.00
Section C, Equipment		
Section D, Travel		24,000.00
1. Domestic	24,000.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		26,000.00
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	16,500.00	
9. Other 2	4,000.00	
10. Other 3	5,500.00	
Section G, Direct Costs (A thru F)		103,345.00
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		103,345.00
Section J, Fee		

OMB Number: 4040-0001
Expiration Date: 04/30/2008

Budget Justification

Budget

Salary	Costs
A. Ken Moore (6%; $108,435)	$13,012
B. Storyline technician (800 hrs; $25/hr)	$20,000
C. Survey Developer (400 hrs; $30/hr)	$12,000
D. Data Analyst (2 cal months at $50,000/year)	$8,333
Travel	
consult on Storyline development	$3,000
administer state survey materials	$6,000
collect video for updating ISSC DVD	$5,000
travel for ISSC conference participants	$10,000
Materials and Supplies	
software	$16,500
Printing	$4,000
Small equipment	$5,500
TOTAL	**$103,345**

Total Project Costs: $103,345

Budget Justification:

SECTION A/B

Salary: Project funds ($6,500) are requested to support Ken Moore, project PI. Ken will dedicated 6% of his time and effort to this project (12%; yearly salary = $13,012). Funds are also requested for an hourly technician that is familiar with the Storyline software (800 hours; $25/hour; total = $20,000) and for an hourly survey developer/analyst that can develop and analyze data collected through the state survey to assess outreach for recreational boaters (400 hours; $30/hour; total = $12,000). In addition, funds are requested for a data analyst (2 calendar months at $50,000; total = $8,333) that will provide Storyline technical assistance as well as to assist in analyzing survey results.

SECTION D

Travel: All travel is domestic. Project funds are requested for travel to "harvest states" for consultation with the Storyline developer as they assist each state with development of a program specific for use in training their harvesters and dealers ($3,000). Funds are also requested to travel to states as the survey materials are administered to assess outreach for recreational boaters ($6,000). Travel funds are also requested to visit specific harvesting state locations for collecting video that will be used to update the current ISSC DVD aimed at overboard discharge and the use of pump stations, as well as to collect pictures that will be archived in the ISSC database for use in developing state-specific harvester and dealer training programs ($5,000). Finally, the ISSC will host a conference to discuss human enteric virus impacts to shellfish growing waters and the use of alternative indicators for management of shellfish growing and harvest waters. Funds ($10,000) are requested to assist with venue costs for this conference and to assist with travel for state personnel and appropriate experts for the meeting.

SECTION F

Other Direct Costs: Project funds ($16,500) are requested for the purchase Storyline software that will be distributed to 12-16 harvest states for developing their state-specific harvester and dealer outreach program. In tandem, project funds are requested to print appropriate materials for (1) a software training manual that can be distributed to the states to assist them with learning to use the Storyline software; and (2) printing of the recreational boater surveys ($4,000). Finally, project funds are requested for small equipment (cameras, associated software) to obtain visuals/video for updating the existing ISSC DVD ($5,500).

Appendix B

United States Department of Agriculture
National Institute of Food and Agriculture
AWARD FACE SHEET

1. Award No.	2.Amendment No.	3. Proposal Number	4. Period of Performance	5. Type of Instrument
2011-68003-30395	7	2014-06165	06/01/2011 through 05/31/2014	Grant

6. Type of Action	7. CFDA Number	8.FAIN	9. Method of Payment	10. CRIS Number
Revision	10.310	20116800330395	ASAP 68003303956800313000	0225445

11.Authority:
7 U.S.C. 450i(b), Section 7406 of FCEA of 2008, P.L. 110-246, AFRI

12. Agency (Name and Address)
Awards Management Division
National Institute of Food and Agriculture/USDA
Washington, DC 20250-2271

13. Awardee Organization
North Carolina State University
Raleigh, NC 27695-7514

14. Program Point of Contact:
Jeanette Thurston
Telephone: 202-720-7166
jthurston@nifa.usda.gov

Administrative Point of Contact:
Adam Anderson
Telephone: 202-401-4185
acanderson@nifa.usda.gov

15. Project Director/Performing Organization
Lee-Ann Jaykus
North Carolina State University
Raleigh, NC 27695-7407

16. Funding:

	Federal	Non-Federal
Previous Total	$14,977,140.00	$0.00
+ or -	$0.00	$0.00
Total	$14,977,140.00	$0.00
Grand Total	$14,977,140.00	

17. Funds Chargeable

FY - FDC	Amount	FY - FDC	Amount
13- 362-68003	$0.00		

18. Title of Proposal
Building Capacity to Control Viral Foodborne Disease: A Translational, Multidisciplinary Approach

PROVISIONS

This Award incorporates the following:

1. The requests contained in Lee-Ann Jaykus's email dated May 8, 2014 have been reviewed by this office and the NIFA cognizant program official. NIFA approves the request as indicated below:
2. Authorization to enter into proposed subcontract agreement with The Interstate Shellfish Sanitation Conference for approximately $103,534, as outlined in the request. The Form AD-1048 @ (http:/www.NIFA.usda.gov/funding/all_forms.html) or other NIFA approved format must be completed by the approved subcontractor and returned to the recipient for retention in the official award file. It is not necessary to send a copy to NIFA-USDA. (Please note that provisions of the Uniform Federal Assistance Regulations (7 CFR Part 3015) apply to this authorization and should flow down to the subcontractor.)
3. The AOR signed letter of commitment, statement of work, budget, and budget narrative for the subcontract to the Interstate Shellfish Sanitation Conference has been received and approved by NIFA-USDA, therefore, grant funds in the amount of $103,534 are released for expenditure from Proposal Number 2013-05502. With this action, all funds for this award are now released.
4. All other Provisions on the Award Face Sheet dated August 27, 2013 and any amendments thereto remain in effect.
5. If you have any questions concerning this action, please contact the Administrative Point of Contact listed above.

FOR THE UNITED STATES DEPARTMENT OF AGRICULTURE

This award, subject to the provisions above, shall constitute an obligation of funds on behalf of the Government. Such obligation may be terminated without further cause unless the recipient commences the timely drawdown of funds; such drawdowns may not exceed one year from issuance date of the award.

Typed Name	Signature	Date
Duane Alphs Authorized Departmental Officer	DALPHS	05/28/2014

NIFA-2009

ATTACHMENT A TO THE NIFA-2009

AWARD NUMBER: 2011-68003-30395

Building Capacity to Control Viral Foodborne Disease: A Translational, Multidisciplinary Approach

Co-Project Directors:

Robert L. Atmar- Baylor College of Medicine

Christine Moe- Emory University

Jan Vinje- Centers for Disease Control and Prevention (CDC)

Jennifer Cannon- University of Georgia

Mary K. Estes- Baylor College of Medicine

Leonard Williams- NC A&T State University

Aron Hall- Centers for Disease Control and Prevention (CDC)

Angela Fraser- Clemson University

Alvin Lee- National Center for Food Safety and Technology

Li-an Yeh- North Carolina Central University

Steve Beaulieu- Research Triangle Institute

From:	Nancy Daniel on behalf of ISSC
Cc:	ISSC
Bcc:	"patricia.klocker@state.co.us"; "michael.bott@state.de.us"; "Shepherd, Sidney"; "kathy.brohawn@maryland.gov"; "jeff.kennedy@state.ma.us"; "scott.gordon@dmr.ms.gov"; Joe Jewell; "chris.nash@des.nh.gov"; "Bruce.friedman@dep.state.nj.us"; "DeRosia-Banick, Kristin"; "wghastba@gw.dec.state.ny.us"; Patti Fowler; "Shannon.jenkins@ncdenr.gov"; "travisb@health.ok.gov"; "dsmith@oda.state.or.us"; "catherine.white@health.ri.gov"; Jerrod Davis; "Rick Porso (rick.porso@doh.wa.gov)"; "ben.stagg@mrc.virginia.gov"; "jillian.fleiger@freshfromflordia.com"; "antonio.kilpatrick@myfwc.com"; "alison.sirois@maine.gov"; "meggan.dwyer@maine.gov"; "kohl.kanwit@maine.gov"
Subject:	NSSP Shellfish Harvester and Dealer Training Programs
Date:	Tuesday, August 26, 2014 3:19:00 PM

In 2011, the ISSC adopted requirements for shellfish harvester and dealer training. The effective date of the requirement was January 1, 2014. To assist States with compliance, the ISSC has developed model harvester and dealer training programs. The final draft of each program is available for your review at the links listed below under 1.

The ISSC has acquired funding to assist States in the development of these programs. Assistance to States from the ISSC is available as follows.

1. A State may utilize the final draft (click on the link above) to achieve compliance in its present form.

   NSSP Shellfish Harvester Training Program

   NSSP Shellfish Dealer Training Program

2. ISSC will provide Articulate Storyline software which will allow the State to customize the training program to include requirements specific to their State.

3. ISSC will provide the State with technical assistance through a contractor to customize the programs for their State. Due to the cost of this assistance, the ISSC will limit the extent of the customizing.

The link below provides a PDF version of each training program which shows the slide and a written narrative.

NSSP Shellfish Harvester Training Program Slide Master with Written Narrative

NSSP Shellfish Dealer Training Program Slide Maser with Written Narrative

Please advise me of the type of assistance which will best meet your needs.

Thank you,
Ken Moore

Ken B. Moore, Executive Director
Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223-1740

Phone: 803-788-7559
Fax: 803-788-7576
Email: issc@issc.org
Website: www.issc.org

TIME/TEMPERATURE QUESTIONS AND ANSWERS

1. A number of dealers ship via a common carrier truck. The truck would make several stops to pick up oysters from different dealers. Each time it would be A3 product that has not been cooled to 50 F. How is the time/temperature recording device requirement handled?

Inquirer comment: My thought is that either each dealer would have to place a time/temperature recording device with their own shipment or they could all get together and arrange with the truck owner to have a single time/temperature recording device in the refrigerated cooler throughout the process. So the truck starts off with a time/temperature recording device and just keeps it in there the whole time. Actually I'm thinking that the truck could be equipped with a device that produces a continuous recording chart then each receiving dealer could look at the chart. Unless we would require that they keep the chart as a record. Hopefully we would allow them to just say in their record that they looked at the chart and it indicated continuous cooling. Of course it's probably not going to be continuous cooling because every time they open the truck door up the temperature will go up some. But that's going to be a reality regardless. I say it's not continuous cooling if the temperature ever goes up when the door opens we're going to have to say one truck can't carry more than one shipment because the only way that's not going to happen is if they never open the door once the first shipment is placed in and the door is closed.

REFERENCE: Chapter IX.05, Chapters XI, XIII, & XIV – Receiving CCP

RESPONSE:
Based on NSSP MO Chapter XIII.01.D(2) the dealer could either opt for a single recording device or the truck's as long as it has "continuing cooling." Rises in temperatures as the door is opened are common in shellstock storage but the overall "continuing cooling" should be demonstrated and can be demonstrated with a single or joint use time temperature recording device. It's an overall "continuing cooling." Either approach can be used as long as every dealer can be provided with the recording device information that meets NSSP MO Chapter XIII.01.A.

- 2. Should NSSP Guide Chapter X.08.A(2) include:
- The date and time of shipment; and
- (e) A statement that all shipping conveyances comply with Chapter IX.04.

RESPONSE:
It could but it would require a proposal to the ISSC to add. Currently it is required as a Transportation Document under NSSP MO Chapter IX.05.

3. Is a shipping document required when a Reshipper goes to a certified dealer to pick up shellstock that is below 50 degrees internal temperature, and then deliver that product directly to his retail customers? If so, who is considered the shipping dealer,

the original certified dealer supplying the product to the reshipper, or the reshipper supplying the product to his retail customers?

REFERENCE: Chapters XI, XIII, & XIV – Receiving CCP

RESPONSE:
NSSP MO Chapter X.08.A.(1) Each shellfish shipment shall be accompanied by a shipping document. Chapter IX.05. also requires a transportation record.

Under NSSP-MO Chapter IX.05, the dealer who sells the product to the reshipper must provide this transportation record and the selling dealer must verify in a transportation record that the truck he puts the product in (even if he doesn't own it) meets NSSP-MO Chapter IX.05.

4. Must firms address the temperature of shellfish at shipping on the transportation record?

REFERENCE: Chapters XI, XIII, & XIV – Storage CCP

RESPONSE:
The temperature of shellfish is not required, but the temperature of the conveyance must be below 45°F prior to shipment.The requirement for Chapter IX.05 deals only with the conveyance.

NSSP MO Chapter IX.05 requires all shipment of SHELLSTOCK be accompanied with documentation indicating time of shipment and conveyances compliance to Chapter IX.04 which is shellstock adequately iced, or in a conveyance prechilled at or below 45F ambient air.

NSSP MO Chapter XIII.D.(2) requires SHELLSTOCK be cooled to meet Chapter XIII.B.(3) or meet Chapter XIII.B.(4) prior to shipment but does not require it on the transportation record unless the Transportation record is also used as a HACCP record to meet the Shellstock Shipping CCP.

5. Does stamping or pre-printing invoices with the following text: "Truck pre-chilled to 45o, shellfish 50o or colder", or, "Truck is pre-chilled to 45 o or cooler" meet the new time temperature transportation record requirements?

REFERENCE: Chapter IX.05

RESPONSE:
NO, per NSSP MO Chapter IX.04 the document must reflect that the presence of ice or that the temperature of the conveyance was observed. A check mark next to a pre-printed statement would be allowed but an observation must be made and indicated. Stamping would suggest that an observation has occurred. A preprinted invoice would not. In addition, the time of shipment must be added as required per NSSP MO Chapter IX.05

6. Regarding calculation of Maximum Temps.

VIII@.02 Shellstock Time to Temperature Controls "C. The Authority shall establish the water or air temperature to be applied to the requirements above for each growing area by averaging the previous five (5) years maximum monthly water or air temperatures"

Does this mean take the Monthly Maximum temperature (1 measurement per month) then average for 5 years OR take the daily maximum temps for each month and average over 5 years (i.e. ~30 measurements per month per year)?

Inquirer Comment: In Rhode Island the way that this is calculated could result in

either 6 months >80degrees or only 2 months. Under the first method of calculation April would exceed the limits even though the average daily maximum temp is only 60.6 and the average daily mean temp is 51.

RESPONSE:
SEND FOR FURTHER REVIEW

7. I don't know where to point to in the Model Ordinance to show that A3 product has to be placed under refrigeration within any particular time frame. The A3 matrix doesn't say anything about refrigeration. The time limits are "Maximum Hours from Exposure to Receipt at a Dealer's Facility." 2009 Model Ordinance IX.02C.(2) required that a dealer place shellstock under refrigeration within 2 hours of receiving them but when the all the changes were made to Chapter IX they deleted that and, as far as I can tell, didn't replace it with anything. The "2 hours at points of transfer thing" only applies "once shellstock have been placed under refrigeration. So do you have something I can point to?

RESPONSE:
You are correct, there is not a requirement that a dealer receiving Shellstock from a harvester that was harvested under Chapter VIII.@.02.A.(3) place shellstock under refrigeration within 2 hours of receiving. Chapter XIII.03.F.(6) requires the following:

All shellstock obtained from a licensed harvester shall be

- Adequately iced;
- Place in a storage are maintained at 45F; or
- Processed within two hours of receipt.(SC/K)

To achieve compliance with Chapter VIII.@.02.A.(1) and (2), the records of a dealer receiving Shellstock from a harvester must reflect that the Shellstock was iced or placed in refrigeration within the time period established in state vibrio plans.To achieve compliance with Chapter VIII.@.02.A.(3), the records of a dealer receiving shellstock from a harvester must indicate that the shellstock was received at the facility within the time periods outlined in Chapter VIII.@.02.A.(3). The refrigeration requirement for shellstock intended for shucking, that is not harvested under a state vibrio plan, can be found in Chapter XI.03.F.(11).Refrigeration is required unless the dealer begins shucking within two hours.For shellstock not intended for shucking, the refrigeration requirements for the dealer can be found in Chapter XIII.03.F.(6). If a dealer is not processing the shellstock, they must immediately ice the shellstock or place the shellstock in refrigeration. If the dealer is processing the shellstock, the processing must be completed within two hours.

8. Is the requirement to record the temperature of the truck a firm is using to transport their shellfish, that it has to be included in the HACCP plan and is a HACCP record? It is my understanding that this is not a HACCP critical limit and does not have to be included in the plan. But the record still has to be kept and available for review.

REFERENCE: Chapters IX.05

RESPONSE:
The shipping dealer has to include the information in Chap IX 04 and 05 for each shipment. It is not considered a HACCP record for the shipping dealer. The information is considered a HACCP record for the receiving dealer and the information must be included in the HACCP plan and maintained as a HACCP record as outlined in NSSP MO Chapter XIII.A.(2).

9. Is the shipping documentation required for surf clams or ocean quahogs that are going to be further processed? Chapter VIII @02 G. exempts ocean quahogs and surf clams from temperature control plans when intended for thermal processing but I do not see an exemption from the transportation documentation. J.H. Miles is questioning MD requiring their MD entity to provide this documentation. All processes are not necessarily thermal, frozen breaded clam strips and frozen raw clams, but none of this product is eaten raw.

RESPONSE:

Chapter VIII @02 (G.) exempts ocean quahogs and surf clams from the requirement of complying with State Vv, Vp, and the (A.)(3.) max hours from exposure to receipt at a dealer's facility only. It does not exempt them from the Chapter IX 05. Transportation Records requirement , which states "All shipments of shellstock shall be accompanied with documentation indicating the time of shipment and that all shipping conveyances comply with the requirements of Chapter IX. 04. This documentation must include a notice of all shellstock harvested under the requirements of Chapter VIII.@.02 A. (3) that has not been cooled to an internal temperature of 50°F (10°C) and indicate the presence of a time/temperature recording device.". If they wish to be exempt from IX 05., it would require a proposal submission to change the MO.

In the Guidance document, it states:

"To comply with the time to temperature requirements for shellstock intended for Wet Storage, Depuration, Post Harvest Processing (PHP), or "For Shucking Only by a Certified Dealer", the dealer must comply with one of the options below:

Option 1

The dealer must shuck or introduce into Wet Storage or Depuration, within the applicable time to temperature controls of Chapter VIII. @.02 A (3) and Chapter XIII .03; or

Option 2

The dealer must place the shellstock in temperature control within the applicable time to temperature controls of Chapter VIII. @.02 A (3) and Chapter XIII .03.

Ocean Quahogs (*Arctica islandia*) and Surf Clams (*Spisula solidissima*) are excluded from the time to temperature controls of State *Vibrio* Control Plans or the matrix outlined in Chapter VIII. @.02 A. (1) (2) and (3). This exclusion applies only when these products are intended for thermal processing. Authorities may exclude other species when intended for thermal processing.

However, there is still not an exemption from transportation documentation required under IX.05.

10. When a firm supplies a TTR with each shipment do they have to also manually document the time of shipment and the temperature of the truck, which will be on the TTR when read at the end destination? I am requiring in MD that the temperature of the shellstock be included on the shipping documentation but firms that are either voluntarily/or customer mandated supplying the TTR want to know if that meets the other 2 shipping documentation requirements. The shipping documentation would read "TTR included in shipment, temperature of shellstock_____."

RESPONSE:
IX.05 specifically states that the transportation record include the time of shipment, a statement that the shipment complies with IX.04, and for VIII.@02.(A.)(3.) not cooled to 50F a statement stating such, and indicate the presence of a TTR. In the example provided, "TTR included in shipment, temperature of shellstock_____, time of shipment_____, a statement that the conveyance is iced/mechanical refrigeration less than/equal to 45F, and a VIII@02.(A.)(3.) statement if necessary" must be included to meet the requirements of IX.05.

11. Dealers in other States are requiring that the shipping documentation be signed by the shipping dealer. One of my dealers almost had a load rejected for this reason. I would appreciate that the ISSC reiterate that shipping documentation is not a HACCP record for the shipping dealer and does not require a signature.

RESPONSE:
The transportation documentation required in IX.05 is not a HACCP record for the shipping dealer, only the receiving dealer, and as such, does not require the shipping dealers signature.

12. Finally, some dealers are refusing to provide the shipping documentation because they drop the product off at transfer station for shipment by a common carrier. Dealers concerns are that they cannot document this information because they are not present when the product is shipped. The receiving dealer is then in violation of his HACCP plan since no documentation is provided. I am not sure how the ISSC wants to address this since the shipping firm may never know the exact time of shipping or be able to document the truck temp or shellstock temp at shipping. It is unlikely that any shipping firm will do this. Even when our firms provide this info on the Bill of Lading the carrier does not always provide it at delivery.

RESPONSE:

The shipping dealer is required to provide the receiving dealer with a transportation document. IX.05 states that it must accompany the shipment but this does not preclude the shipping dealer from also providing the information via fax or scanned/emailed to the receiving dealer. In this specific example, a prudent shipping dealer would include a TTR so that the receiving dealer had evidence that continuous cooling had occurred during shipment or that the shipment was maintained at 45F or below for the entire shipment time allowing them to meet the CLs at the receiving CCP. If a dealer is relinquishing control of the product, they must find a way to meet the requirement. Receiving dealers should reject the product if paperwork is not present.

Interstate Shellfish Sanitation Conference (ISSC)
Male Specific Coliphage (MSC) Informational Meeting
August 18-19, 2014
Charlotte, NC

I. Introduction

The ISSC held a MSC Informational Meeting in Charlotte, NC. The purpose of this meeting was to discuss the appropriate use of MSC as an enteric virus risk indicator in the National Shellfish Sanitation Program (NSSP). Currently, MSC is used in the NSSP to evaluate sewage spills. Previous proposals attempted to expand MSC to other types of classification. This meeting brought together expert panelists on MSC to present current data regarding the effectiveness of MSC as an indicator of NoV. This format allowed the committee to discuss the most appropriate expanded uses of MSC after hearing supporting science.

II. Expert Panelists

The ISSC invited several panelists with expertise in the use and applicability of MSC as an indicator of the risk of enteric viruses in shellfish.

A. Bill Burkhardt

B. Kevin Calci

Kevin Calci received his BS and MS degree in Microbiology from the University of Rhode Island in the early 1990's, where water pollution microbiology was the focus. He was commissioned in the US Public Health Service as an Environmental Health Officer in 1993 and stationed at the FDA's Northeast Technical Services Unit in Davisville, RI, concentrating primarily on microbial contamination in shellfish growing areas. He holds a NEHA credential as a Registered Environmental Health Specialist. Currently, CDR Calci is stationed at the FDA's Gulf Coast Seafood Laboratory in Dauphin Island, Alabama, where he combines microbial detection techniques for Norovirus and male-specific coliphage with novel hydrographic equipment to accurately model human viral loading in proximity to municipal waste water treatment plants. CDR Calci is the subject matter expert responsible for coordinating the wastewater treatment module of the US/Canadian Norovirus in Molluscan Shellfish Risk Assessment.

C. Thomas L. Howell

Thomas L. Howell has an undergraduate degree in General Science from Union College and a graduate degree in Physical Oceanography. He and his wife established and have operated Spinney Creek Shellfish, Inc., a shellfish depuration company since 1983. Spinney Creek Shellfish, located in Eliot, Maine, has one of a very small number of certified private shellfish laboratories. In 2005, when the U.S. F.D.A. introduced a proposal for change to the National Shellfish Sanitation Program's Model Ordinance to incorporate the Male Specific Coliphage method, he saw opportunities. He recognized that MSC could have the effect of opening areas that are presently closed due to proximity to waste water treatment areas. Tom took it upon himself to learn much of what there is to know about MSC. He built an extensive library of MSC papers. He validated the MSC method for soft shell clams, American Oysters and Quahogs and in collaboration with scientists at the F.D.A.'s Gulf Cost Seafood Laboratory he has conducted research on the depuration rates of MSC and Norovirus. In addition, he worked with FDA and the Maine Department of Marine Resources to establish protocols for specialty depuration using MSC as an additional tool. He has been invited as a technical speaker to present MSC information at the Interstate Shellfish Sanitation Conference, the Northeast Shellfish Sanitation Conference, the International Conference on Molluscan Shellfish Safety and others.

D. <u>Lee-Ann Jaykus</u>

E. <u>David Lees</u>

David is the senior food safety advisor in the Food Safety group at Cefas Weymouth laboratory, UK. David has more than 30 years experience in human health microbiology including disease diagnosis and monitoring, virological research, algal biotoxin monitoring, statutory related programs and reference laboratory activities. David is Director of the European Union Reference Laboratory (EURL) for bacterial and viral contamination of bivalve molluscs. A key research remit of the EURL has been to improve controls for enteric virus contamination of shellfish. The EURL pioneered the use of FRNA bacteriophage as a potential 'viral indicator' for shellfish sanitation and has published key papers in the field. A critical aspect has been the comparison of FRNA bacteriophage with norovirus and *E.coli* to understand the potential utility of this approach. More recently the EURL has focused on standardization and application of quantitative PCR methods for norovirus and hepatitis A virus for potential use in food safety controls.

F. <u>David Love</u>

Dave Love, PhD, MSPH is an environmental microbiologist with an interest in agriculture, water quality, food safety, and public health. Dr. Love has been an Assistant Scientist in the Department of Environmental Health Sciences at the

Johns Hopkins Bloomberg School of Public Health (JHSPH) since 2011, and project staff since 2009 at the Johns Hopkins Center for a Livable Future (CLF). Prior to joining Johns Hopkins, Dr. Love was a postdoctoral fellow in the Department of Civil and Environmental Engineering at the University of California Berkeley and at the Department of Environmental Sciences and Engineering University of North Carolina (UNC). At Berkeley Dr. Love studied tertiary wastewater treatment systems in the Salinas Valley, California, which enabled more water to be recycled in the region. At UNC and Berkeley he studied human exposure to microbes at several beaches in the United States. This research helped informed the Recreational Water Quality Criteria released by the EPA in 2012. At Johns Hopkins, Dr. Love has published on issues related to aquaculture and food production in leading engineering and environmental science journals. He also focuses on the use of antimicrobial drugs in food production, and the health implications of antimicrobial resistance and drug residues and in meat, dairy, and seafood.

G. Kim Reese

Dr. Kimberly Reece is a professor of marine science at the Virginia Institute of Marine Science and chair of the Aquatic Health Sciences Department. She has a bachelor's degree in microbiology from the University of Rochester and a doctorate in biochemistry, molecular and cellular biology from Cornell University. She has more than 20 years experience working in estuarine systems studying the genetics and ecology of pathogens with over 100 peer-reviewed publications. The focus of her laboratory is molecular genetic analyses of shellfish, shellfish pathogens and human pathogens transmitted through shellfish. Her current research projects include optimization of methods for detecting human pathogenic norovirus in shellfish, examining the environmental persistence of norovirus and adenovirus and studying the ecology of *Vibrio* species in shellfish, water and sediments; all projects aimed at lowering human health risk associated with shellfish consumption. In collaboration with Dr. Howard Kator she conducted studies comparing the persistence of FRNA coliphage and norovirus demonstrating that in an estuarine environment FRNA coliphage inactivation rates were higher and more variable than norovirus inactivation rates in both *in situ* studies done in the field and *in vitro* laboratory experiments, with norovirus consistently being more persistent than FRNA coliphage.

H. Chris Roberts

Chris Roberts is a Regional Manager in Environment Canada's Marine Water Quality Monitoring Program based in Halifax, Nova Scotia. Chris was educated in water resources engineering at the Technical University of Nova Scotia (now part of Dalhousie University). He is responsible for delivery of

the shellfish growing area classification component of the Canadian Shellfish Sanitation Program (CSSP) in the four Atlantic Provinces of New Brunswick, Newfoundland and Labrador, Nova Scotia and Prince Edward Island. Chris leads a national engineering team conducting comprehensive evaluations of wastewater systems impacting shellfish growing areas across Canada. He is an Assessment Team member of the US-Canada Food Safety Risk Assessment on Noroviruses in Shellfish and a member of the ISSC Growing Area and Foreign Relations Committees. Chris oversees an on-going MSC wastewater sampling project that informs the development and refinement of technical policy used by wastewater assessment engineers to recommend appropriate growing area classification under the CSSP. The use of MSC as an indicator of enteric viruses in sewage has enabled the CSSP to develop effective conditional management plans based on wastewater system operation and appropriately-sized prohibited zones to mitigate viral contamination risk in adjacent growing areas.

I. Chip Simmons

Dr. Simmons maintains joint appointments in the Departments of Biological and Agricultural Engineering and Food, Bioprocessing, and Nutrition Sciences at North Carolina State University. His expertise is in environmental and public health microbiology, with research efforts focusing on the development and implementation of methods to detect and quantify bacterial, viral, and parasitic pathogens and indicator organisms in different matrices, including environmental water, soil, and air. His current research interests lie in the areas of pre-harvest food safety, worker health and personal hygiene during harvest, and disinfection of irrigation and process water used for fruit and vegetable production. Dr. Simmons' extension and outreach efforts target fresh produce production, packing, and processing as well as molluscan shellfish safety. His goals are to build scientific capacity and human relationships that will support increased, sustained efforts in food virology as a member of the USDA-NIFA Food Virology Collaborative, whose long term goal is to produce a measurable reduction in the burden of viral foodborne disease in the U.S. Dr. Simmons' outreach efforts are to engage stakeholders for translating and disseminating research findings related to food borne viruses into practical solutions for target audiences through updated extension/outreach materials.

III. Field Study Overview

The expert panelists were asked to respond to a number of questions (See Attachment A). Several of the expert panelists who had field experience utilizing MSC presented results from field studies. Below is a synopsis of the studies that were presented.

A. Tom Howell, Spinney Creek Shellfish, Inc.:

Tom presented three field studies. The first was conducted in New England using samples from the Royal River, Fore River, and Presumpscot River in a multi-year collaboration with Spinney Creek Shellfish, FDA Gulf Coast Shellfish Lab, Maine Department of Marine Resources, and Massachusetts Division of Marine Fisheries. The second was conducted solely in the Royal River and tested spatial variation studies and the dilution model in collaboration with Spinney Creek Shellfish, FDA Gulf Coast Shellfish Lab, Greg Goblick's Dye Study Group, and the Maine Department of Marine Resources. The third was conducted at multiple sites in Marblehead Harbor, MA in collaboration with Spinney Creek Shellfish, MA Department of Marine Fisheries, UNH Sea Grant, FDA Gulf Coast Shellfish Lab, and Maine Department of Marine Resources.

B. David Lees, Centre of Environmental Fisheries and Aquatic Science:

David presented multiple studies conducted throughout the EU, including the UK Harvest Area Study (circa 2001) and data from the Centre for Environment, Fisheries & Aquaculture Science (2000-2003). These studies addressed the applicable use of MSC as an indicator in classifying shellfish growing areas.

C. Kevin Calci, US FDA Dauphin Island:

Kevin presented two potential areas in which the expanded use of MSC could be applied: wastewater treatment plant efficiency and as a shoreline survey tool. Data from treatment plants and shoreline surveys came from numerous locations across the US.

D. Chris Roberts, Environment Canada Marine Water Quality Monitoring:

Chris presented MSC data regarding different wastewater treatment plant log reduction values for MSC compared to fecal coliform in Canada. Also, he described the effect seasonality has on MSC.

E. Kim Reece, Virginia Institute of Marine Science:

Kim presented an *in vitro* and *in situ* study on whether MSC's are suitable to assess stability (temperature/sunlight) of enteric viruses in the marine environment. Also mentioned was a protocol for distinguishing infectious from non-infectious NoV.

IV. <u>Questions Answered by Panelists</u>

A. Tom Howell

7. What is the estimated rate of false positives or false negatives utilizing existing MSC analysis?

   The chances of false positives are low due to the specificity of bacteriophages. These are for meat testing.
   See slide 14 of David Lees "Answers to questions" PowerPoint.
   Dave Love agreed citing methods comparisons EPA 1601 and EPA 1602 from a study in 2003-2005. EPA detected 60% of samples positive and 1602 was much lower at 24%. (%%%%He did not reference the name of the study or where to find it.)

10. What are the estimated costs to the industry, nationwide as a result of adopting more stringent growing area standards?

    There was not agreement that MSC would be a more stringent standard, and MSC is not being recommended to replace the existing indicator. The impact of using MSC adjacent to WTPs may not reduce harvestable acreages and would not result in a cost to the industry.

14. What do we know about the dynamics of viral depuration rates and what factors/processes influence the rates of inactivation or elimination of enteric viruses or MSC?

    Temperature and season are influencing factors. As levels increase in winter, depuration becomes more difficult as well. For summer the opposite occurs with lower levels and more efficient depuration.
    Also see question 6.

15. Since warm temperatures are required for shellstock to "purge" during relay or depuration (must be actively pumping) and MSC levels are low when temperatures are warm, how can it be an effective measure to reduce relay and depuration times?

    Winter months would probably require the heating of water and would not be economically feasible in tanks. It is *possible* to make it work year-round, but most economically in warmer months.

29. Did any studies determine the background levels of MSC in shellfish in prohibited areas/closed safety zones that are continuously exposed to adequately treated effluent from a wastewater treatment plant?

    Yes
    Tom Howell's PowerPoint Presentation: See graph on slide 4. The graph illustrates seasonal variation in multiple locations.

30. Any studies/data on the background levels of MSC in shellfish in the conditionally approved and/or approved areas, lying down stream/down tide from the adjacent or nearby prohibited area/closed safety zone around the sewage outfall that are continuously exposed to some amount of adequately treated effluent from a wastewater treatment plant?

    Kevin Calci indicated that the wording of this question, particularly "adequately treated", does not allow for a definitive answer.

35. Did any studies involve determining the levels of MSC in shellfish in an approved area, which is not near a WWTP outfall and thus not downstream/down tide from an outfall and not regularly exposed to dilute, adequately treated effluent from a WWTP, but which had been temporarily affected by raw, untreated sewage discharged from a break in a sewage collection line or pump station overflow, that is adjacent to that approved area but which normally sends raw sewage to a WWTP that discharges to another area?

    *See answer to question 30.

B. Kevin Calci

2. There is some evidence that MSC replicate in the environment in absence of a pollution source. How does this impact its use as an indicator of viruses?

    There is no evidence that MSC grows in the environment.
    Dave Love: Environmental conditions make it unlikely for this to happen.

11. What is the estimated reduction in the number of days opened to harvest of conditionally approved shellfish growing areas, anticipated as a result of adopting more stringent growing area standards?

    Instead of this being "more stringent" it could perhaps be a benefit by being "less stringent".

12. What are the estimated reductions of approved or conditionally approved shellfish growing areas acreage, nationally, anticipated as a result of adopting more stringent growing area standards?

    See question 10.
    See slides 9 - 11 of David Lees "Answers to questions" PowerPoint.

20. Researchers have been looking for suitable Norovirus surrogates for decades, however each of the candidates (culturable viruses such as Feline calicivirus, Murine norovirus, Tulane virus) has drawbacks because

apparently they don't respond to treatments (HPP, antiseptics, UV, chlorine etc.) in the same way as NoV. Why is MSC a superior surrogate to the other viral candidates?

MSC is a cheap assay. Also, see questions 9 and 13.
Lee-Ann Jaykus clarified MSC is an indicator, not a surrogate. The other viruses mentioned here are surrogates.

33. What applicability is there when the discharge is other than "raw, untreated sewage" but involves, for example, partially-treated sewage that was chlorinated?

MSC is applicable when discharge is other than “raw untreated sewage”. The levels of chlorination presently used do not efficiently eliminate NoV or MSC.

34. Did any studies determine the change in the levels of MSC in shellfish (any species) over various intervals (days) after a discharge of raw, untreated, non-disinfected sewage? Of partially treated sewage, with disinfection by chlorination? Disinfection by UV radiation?

Information was not available to differentiate all of the treatment options listed, however Bruce Friedman provided data from the MSC samples following Hurricane Sandy that shows a relationship for water temperature and depuration of MSC. The data can be found at: www.nj.gov/dep/bmw/sandy.html.

C. Bill Burkhardt

1. Little is known on the distribution of phages in growing areas. What is the significance of background levels in the absence of sewage?

MSC is only found in an area affected by human sewage from large populations.

3. What differences in winter vs. summer, if any, were found in the levels of MSC in water in areas of those different classification types around WWTP outfalls?

In David Lee’s PowerPoint “Answers to questions” slide 2 indicates fewer outbreaks occurring in the summer months than in the winter.

9. How hard is it to learn the MSC assay, what is the cost per sample and are labs being validated independently to ensure that methods are repeatable between operators and labs?

Fairly easy to do. Initial costs will depend on available lab equipment. A refrigerated high speed centrifuge would cost around $8k-10k.

16. Does the presence of food particles in the water influence depuration rates?

Yes. Shellfish in artificial seawater versus natural seawater had different effects on coliphage but not on fecal coliform. If food is present, shellfish feed and depurate more readily.

32. MSC are rarely detected in human feces, suggesting that their presence in water or shellfish meats do not necessarily indicate human fecal pollution. This needs further study. What size waste water treatment plant or size of human population served is too small to apply MSC?

Dave Love said that in a large population around 5% carry MSC.

D. Chris Roberts

4. What differences in winter vs. summer, if any, were found in the background levels of MSC in shellfish (any species) in areas of the different classification types around WWTP outfalls which are continuously exposed to some amount of adequately treated effluent?

See answer to question 3.

5. Do the accepted levels for regulatory decision making in the US and internationally vary by season or temperature?

The only established level that exists is for assessing the impact of waste treatment plant failure or collection system failures. There is not a seasonal or temperature variable.

21. Is the correlation between NLVs and other enteric viruses and MSC known? If known, how is the correlation impacted by type of treatment, size of plant, and environmental and seasonal conditions at the discharge point. Is MSC a good indicator of NLVs or norovirus under all conditions?

See answer to question 20 and 13.

23. What are the limits in using MSC as an indicator of enteric virus concentrations in growing area overlay waters and shellstock?

See answer to question 20

28. How shall we consider the seasonal effects on efficacy of MSC as an indicator of the presence of pathogenic viruses: i. Variations in human population contributing to the WWTP? Perhaps very low in winter, ~15% of summer levels; ii. Persistence of MSC in the environment (water and/or shellfish)?; iii. Feeding activity of different shellfish species? Very low to inactive in winter, when water temps drop below 50^0F down to 30^0F.

    See answer to question 20 and 3.

31. Do MSC levels in water and molluscan shellfish reflect the magnitude (dilution) of wastewater contamination? Do they overestimate or underestimate the level of contamination?

    See answer to question 20 and 6.

E. Kim Reece

6. Are MSC's suitable to assess stability (temperature/sunlight) of enteric viruses in the marine environment?

    See slides 2 – 5 in Kim Reece's "Reece Questions ISSC" PowerPoint.
    At 20°C-30°C, there is a difference in inactivation rates. For the seasonal data, inactivation rates were more comparable in winter between FRNA coliphage and treated norovirus.
    Dave Love mentioned the difference between DNA-MSC and RNA-MSC and whether these should be considered differently.

19. What is the relationship or correlation between live infectious norovirus and MSC?

    Also, see David Lees PowerPoint presentation in response to his questions (slide 13). This data compares MSC levels, *E. coli* levels, and norovirus outbreaks. There was a relationship to MSC and NoV outbreaks.

22. MSC testing detects infectious agents while current RT-qPCR assays likely detect infectious and non-infectious NoV. Does this level of potential overestimation by RTqPCR err on the side of public health safety; is this overestimation acceptable? If not, why?

    Yes, but more work could be done on the protocols.

25. Is there a general association between MSC and NoV levels in naturally occurring shellfish? Is there an association between these levels and rates of illness? Is this association season/temperature association?

Kim Reece's data did not provide correlation between MSC and NoV. See her slides in "Reecequestion2_ISSC". There was no association between MSC and rates of illness.
See slides 2 - 5 of David Lees "Answers to questions" PowerPoint.
Also, see answer to question 3.

F. David Lees

3. What differences in winter vs. summer, if any, were found in the levels of MSC in water in areas of those different classification types around WWTP outfalls?

   Although the UK using *E. coli* in shellfish meats for classification, differences were found.
   See slides 2 - 5 of David Lees "Answers to questions" PowerPoint.
   Kevin Calci's slides did not have winter versus summer data.

8. What are the options for reducing the lower limits of quantification in existing analysis methods for MSC in water?

   Adjust sensitivity.
   See slide 7 of David Lees "Answers to questions" PowerPoint. Dore et al., 2003.

12. What are the estimated reductions of approved or conditionally approved shellfish growing areas acreage, nationally, anticipated as a result of adopting more stringent growing area standards?

    See answer to question 10.
    See slides 9 - 11 of David Lees "Answers to questions" PowerPoint.

27. What is the relationship or correlation between illness and MSC?

    See slides 13 - 16 of David Lees "Answers to questions" PowerPoint

G. Dave Love

7. What is the estimated rate of false positives or false negatives utilizing existing MSC analysis?

   See answer to question 7 for Tom Howell.

13. What are the limitations of the MSC assay and when should it not be used? (aside from non-point source pollutants)?

Compared to fecal coliform, MSC is much more similar to NoV. MSC is also an inexpensive assay.

17. What differences between shellfish species (oysters, hard clams, mussels and soft clams), if any, were found in the levels of MSC) over various intervals (days) after the discharge of raw, untreated, non-disinfected sewage ended? Seasonal differences in uptake and purging of MSC in different species?

    Kevin Calci: Generally, oysters have the highest levels, then clams, then mussels.

18. How do different species eliminate NoV or MSC? What is the impact of temperature? or more specifically, what do we know about the elimination of NoV and MSC at temps below 50F for hard clams and oysters?

    See answer to question 14 and 15.

24. Do MSC accurately reflect the bioaccumulation and elimination rates observed by NoV from molluscan? How do these rates of accumulation and elimination compare to those by fecal coliforms and E. coli? Is there a season/ temperature association?

    Depuration studies were repeated month to month for E.coli and MSC to see if there was any difference in depuration rates due to environment temperature and no difference was found.
    See slides 2 – 5 of David Lees "Answers to questions" PowerPoint.

26. NoV appears to be rapidly inactivated in summer by UV light. Is the same true for MSC?

    Yes, viruses are sensitive based on the size of their genome. Viruses with bigger genomes die sooner. DNA is more sensitive due to thymine nucleotide.

H. Unassigned

36. 11-102 – Use of shellstock meat samples to define and determine prohibited areas around treatment plants without conducting dye dispersion studies or models may not provide equivalent protection. Without knowledge of the hydrographics impacting the discharge dispersion and dilution, how can the Authority determine where shellstock samples should be collected? How many, how often, what time of year should shellstock be sampled? How often would meat sampling need to occur to be able to account for poor performance or temporary loss of disinfection?

See Committee Recommendations

37. Questions re 11-101 Does size matter? Do we have the right kind of information to determine what a "large" spill is? How does "partial treatment" impact MSC levels in effluent? Differences at sewage treatment plants may produce a vast number of different quality of effluent labeled as "partially treated effluent", how would that be defined?

See Committee Recommendations

V. Expert Panelists Consensus

A. MSC should not be used to replace Fecal Coliform as an indicator for shellfish growing area classification.

B. MSC could be used in conjunction with sanitary surveys to assess impacts of waste treatment plant failures (presently in the NSSP).

C. MSC could be used in re-opening conditional growing areas adjacent to waste treatment plant outfall after waste treatment plant bypass or malfunction after 7 days.

D. MSC could be used to evaluate impact of rainfall events for combined sewer systems. Based on the efficiency of the plant, it could be used for both water quality and shellfish testing.

E. MSC could be used to evaluate quality of waste treatment plant effluent for determining the size of a prohibited, restricted, and conditionally approved area adjacent to waste treatment plant outfalls. This would include determining the size of areas where harvesting for relaying and depuration could occur.

1. Differential wastewater samples for determining waste treatment plant performance with regards to viruses under various flow conditions

2. Differential wastewater samples for determining waste treatment plant performance with regards to viruses for as critical input for dilution models and hydraulic modeling

F. MSC could be used as an indicator for sampling and classification of shellfish growing area adjacent to waste treatment plant outfalls as follows:

1. Assessment tool to determine viral persistence in shellfish meats harvested from growing areas adjacent to waste treatment plant outfall for determining seasonal, spatial, and meteorological variation.

2. Verification tool to determine viral persistence in shellfish meats harvested from growing areas adjacent to waste treatment plant for ground truthing the dye study and dilution model.

G. MSC could be used in source water tracking for shoreline survey problems associated with waste treatment plant collection systems and pump stations.

H. MSC, in conjunction with fecal coliform, could be used as an optional indicator for sampling to determine effectiveness studies and process controls for relaying and container relaying.

I. MSC, in conjunction with fecal coliform, could be used as an optional Indicator for sampling to determine effectiveness studies and process controls for depuration plants.

VI. Committee Recommendations

A. Should MSC be used to replace Fecal Coliform as an indicator for shellfish growing area classification?

- No recommendation.

B. Should MSC be used to assess impacts of raw untreated sewage discharged from a large community sewage collection system or wastewater treatment plant failures (presently in the NSSP)?

-

C. Should MSC be used in re-opening conditional growing areas adjacent to waste treatment plant outfall after waste treatment plant bypass or malfunction after 7 days.

- The Committee supports the concept of this possible use of MSC in the NSSP and recommends a work group be formed to develop proposal language for Committee review.

D. Should MSC be used to evaluate impact of rainfall events for combined sewer systems?

- The Committee recommends adding this item to the work group charge (see 3. recommendation above).

E. Should MSC be used to evaluate quality of waste treatment plant effluent for determining the size of prohibited, restricted, and conditionally approved area adjacent to waste treatment plant outfalls? This would include determining the size of areas where harvesting for relaying and depuration could occur.

1. Differential wastewater samples comparing influent MSC levels to effluent MSC levels for determining waste treatment plant performance with regards to viruses under various flow conditions

2. Differential wastewater samples comparing influent MSC levels to effluent MSC levels for determining waste treatment plant performance with regards to viruses for as critical input for dilution models and hydraulic modeling

- The Committee recommends support of the concept of using differential MSC in wastewater sampling as an optional assessment tool for determining viral wastewater treatment plant performance
- The Committee recommends that a workgroup be formed to develop proposal language for Committee review.

F. Should MSC be used as an indicator for sampling and classification of shellfish growing area adjacent to waste treatment plant outfalls as follows:

1. Assessment tool to determine viral persistence in shellfish meats harvested from growing areas adjacent to waste treatment plant outfall for determining seasonal, spatial, and meteorological variation.
2. Verification tool to determine viral persistence in shellfish meats harvested from growing areas adjacent to waste treatment plant for ground truthing the dye studies and dilution model.

- The Committee recommends support of the concept of using MSC in shellfish meat samples as an optional assessment tool to determine seasonal viral persistence in shellfish meats harvested from growing areas adjacent to waste water treatment plant outfall.
- The Committee recommends that a workgroup be formed to develop proposal language, to include the development of a sampling regime, for Committee review.
- The Committee discussed the relationship of WTP size to the applicability of using MSC. The workgroup is requested to address this concern in the proposal development

G. Should MSC be used in source water tracking for shoreline survey problems associated with waste treatment plant collection systems and pump stations?

- No recommendation. The NSSP does not require source water tracking. States choosing to conduct source tracking have the discretion to use MSC.

H. Should MSC be used as an indicator for sampling to determine effectiveness studies and process controls for relaying and container relaying?

- The Committee recommends support of the concept of these uses and recommends that a workgroup be formed to develop proposal language for Committee review.

I. Should MSC be used as an indicator for sampling to determine effectiveness studies and process controls for depuration plants?

- The Committee recommends support of the concept of these questions and requests a workgroup be formed to develop a proposal for Committee review.

CONTRACT

Between

Interstate Shellfish Sanitation Conference
and
New Jersey Department of Environmental Protection
Bureau of Marine Water Monitoring

This Contract shall be effective from October 1, 2014 to August 31, 2015, between the Interstate Shellfish Sanitation Conference, (hereinafter referred to as ISSC) and the New Jersey Department of Environmental Protection Bureau of Marine Water Monitoring (hereinafter referred to as the Contractor).

The parties to this Contract agree as follows:

I. SCOPE OF WORK

Identify and evaluate the effectiveness of techniques and practices that could potentially reduce the risk of Vibrio illnesses. The study will offer viable control options for the shellfish industry that will reduce risk of Vibrio illnesses. The study will consider issues associated with the effects of water temperature on initial levels at harvest and the effects of post-harvest temperature control as a means of reducing risk of illness. The detail of this work is in the Proposal which is a part of this Contract.

II. TIME OF PERFORMANCE

This Contract shall be effective from October 1, 2014 and reported on by August 31, 2015. A final report shall be submitted within thirty (30) days of the end of the contract period.

III. COMPENSATION

The total amount of the contract shall be Twenty Four Thousand Four Hundred Nineteen and 32/100 ($24,419.32) dollars.

IV. METHOD OF PAYMENT

The initial payment shall be for one-half of the contractual amount. The balance is payable upon completion of the contract and the submission of an acceptable final report.

V. TERMS AND CONDITIONS

A. The Contractor shall agree to make positive efforts to utilize the services and products of small and minority owned businesses and individuals where applicable.

B. Any changes to this Contract, which are mutually agreed upon between ISSC and the Contractor shall be incorporated in written amendments to this Contract.

C. The Contractor shall maintain and retain all records and other documents relating to this Contract for a period of twenty-four (24 months from the date of final payment under the Contract, and shall make the documents available for inspection and audit by authorized ISSC and Federal officials.

D. No person shall be excluded from participation, be denied the benefits of, or be subjected to discrimination in relation to any activities carried out under this Contract on the grounds of race, color, sex, religion or national origin.

E. All project deliverables included on Page 7 of 18 of the NJDEP Bureau of Marine Water Monitoring Proposal (attached) shall be completed. In the event all deliverables are not fully rendered as provided for in the Contract, any monies which have been paid by the agency under the Contract must be refunded to ISSC.

F. The contractor will submit a progress report no later than June 15, 2015. This progress report shall be a summary of activities completed (a brief summary of no more than two (2) pages).

G. Notwithstanding any other provisions of the Contract, the parties hereto agree that the charges to ISSC by the Contractor are payable from federal grant monies. In the event sufficient grant monies are not made available to ISSC to pay the charges hereunder, this contract shall terminate without further obligation of ISSC. In such event, the ISSC shall certify to the Contractor the fact that sufficient funds are not available to ISSC to meet the obligations of the Contract and such written certification shall be conclusive upon the parties.

H. The Contractor certifies that he/she shall not engage in the unlawful manufacture, distribution, dispensation, possession or use of a controlled substance in the performance of this Contract. This certification also applies to any individual employed by the Contractor.

I. The performance of work under this contract may be terminated by the Executive Director, ISSC, in accordance with this clause whenever he shall determine that such termination is in the best interest of the ISSC. The ISSC shall pay all reasonable costs associated with this Contract that the Contractor has incurred up to the date of

termination of the contract. Two (2) weeks advance notice of the Contract termination will be provided by the Executive Director, ISSC. Either party may terminate this Contract by giving written notice at least 14 days prior to the effective date of such termination.

J. All records, documents, and reports developed in the performance of this contract shall be the property of and available to the ISSC for its use without payment of royalty or additional cost and shall not be subject of an application for a copyright by, or on behalf of, the contracted Contractor.

VI. The Contractor shall deliver to the ISSC, on or before the final date of this Contract, one electronic copy (MSWord) and three hard copies of the final report.

The parties to this Contract hereby agree to any and all provisions as stipulated above.

AS TO ISSC	AS TO THE CONTRACTOR
BY: _____	BY: _____
TITLE: _____	TITLE: _____
DATE: _____	DATE: _____
WITNESSES:	WITNESSES:
_____	_____
_____	_____
MAILING ADDRESS:	MAILING ADDRESS:
209-2 Dawson Road Columbia, SC 29223-1740	_____ _____
EMPLOYER ID#:	EMPLOYER ID#:
52-1656630	_____

NJDEP Bureau of Marine Water Monitoring

Proposal for Techniques and Practices for Vibrio Reduction

Submitted to the ISSC Interstate Shellfish Sanitation Conference

July 31, 2014

EXECUTIVE SUMMARY

Aware of the relationship between temperature and prevalence of pathogenic strains of *Vibrio parahaemolyticus* and *V. vulnificus*, the Bureau of Marine Water Monitoring of New Jersey Department of Environmental Protection is proposing a study that will identify and evaluate various oyster handling practices/techniques that could potentially reduce the risk of Vibrio illnesses. The handling methods that we shall be looking at are as follows:

a. Immediate cooling on ice after harvesting before analysis;
b. Shading of oysters for 6-7 hours before analysis;
c. Shading of oysters for 6-7 hours and refrigerated overnight before analysis;
d. Analysis of oyster from harvester; and
e. Tracking and analysis of same oyster lot from retail establishment.

Little is known regarding the fate of *V.p.* and *V.v.* after it leaves the certified dealer. This study will continue to look at the fate of *V.p.* and *V.v.* post-harvest, but also gather info regarding *V.p.* and *V.v.* growth after it leaves the certified dealer end route to the consumer by tracking product to a retail establishment. We will collect samples of oysters from commercial harvesters after harvest, collect samples prior to shipment from the certified dealer (same lot if practical), and work with the FDA to track and collect samples of the lot (same lot if practical) at its final destination (retail establishment). If the same lot is not available, we will analyze retail samples and compare them to data collected on the nearest date.

All samples will be tested for total V.p. (tlh+), pathogenic V.p (tdh+ and trh+) and *V. vulnificus* (vvh) using Official FDA BAM chapter 9 and Nordstrom *et al*., 2007. We plan to start the execution of this proposal from August 2014 for handling methods a-c above while sampling from commercial harvesters d-e will commence from May/June 2015 through August 2015.

APPROACH AND METHODOLOGY

The study aim is to look at the relationship between water temperature, air temperature and salinity as it affects the total *V.p.* (tlh+) and pathogenic *V.p.* (tdh+ and trh+) strains. We will also be looking at the levels of total *V.p.* and pathogenic strains along the distribution chain (harvest to retail).

The collection time frame and sample sites for Vibrio parahaemolyticus (*V.p.*) presence in the oyster tissue will specifically take place in the month of August 2014, and from May through August 2015 at various Delaware sub tidal commercial harvest locations. Although June through August are traditionally considered the months for *V.p.* bacterial sampling, May has been added in in an attempt to analyze and compare various parameters along with *V.p.* presence in oyster tissue, during time frames preceding and following oyster spawning.

Sub tidal collection is proposed to take place four times during each month for Delaware Bay. Two of the sampling events will be performed by the Bureau's staff, from active commercial harvest areas; this sampling is to continue previous analyses on New Jersey's Harvest Practices. The other two sampling events will require the collection of Oysters from a commercial harvester that will be used to monitor the effects of handling, and will cover from harvest to retail. Each sampling event will require one field day for collection, and three consecutive days of lab time for preparation and analysis. During the study period, animal [Oyster – Crassostrea virginica (Cv)] will be analyzed for *V.p.* using Official FDA BAM chapter 9 and Nordstrom *et al.*, 2007 for the enumeration of genes, specific for total and pathogenic *V.p.*

The acquisition of oysters will require the collection of sample sets when visiting each site. For a sub tidal site in Delaware Bay, one of nine sites (harvest/quota dependent) will be gathered each week from May to August. Each visit requires the collection of 45 larger oysters, which will be used for three different harvest/post-harvest handling method comparisons. Each method will examine 15 oysters. The exact methodology for collection in sub tidal waters is detailed below:

1) Label all plastic shellfish bags prior to arriving at sample location(s) with station ID's and handling method letters. Use an indelible marker (e.g., Sharpie) on Autoclave Tape (striped tape acquired from bacteriological lab) that is placed on the outside of plastic bag.

2) Prior to oyster collection you will have acquired an insulated ice chest/cooler and placed approximately two inches of ice on the bottom. On top of that ice you will place a raised rack (e.g., a sample bottle rack from bacteriological lab) where you can place your site collected oysters' samples. Oysters should be covered with bubble wrap and layers of ice packs placed over top of the bubble wrap.

3) Verify site location w/ GPS and attempt to sample within a half mile of the general GPS coordinates shown on lab/field sheets for sub tidal locations.

4) Oysters can be harvested by dredging or tonging with subsequent hand culling for placement in plastic bags for sub tidal waters.

5) Cull oysters, selecting best size for lab processing (attempt to select larger specimens).

6) For each site, collect 15 larger species for each required handling method.

7) Oysters should be cleaned, removing mud, macro algae, debris, etc.
8) Place oysters in a sealed plastic bag and place in cooler as noted in step 2 above.

9) Plan to collect shellfish for delivery to process lab within five hours for Delaware Bay.

Sample collection and analysis will also require acquisition of air temperature, water temperature, DO, salinity, pH, and out of water shell temperature from the collection site. Sub tidal waters require the recording of water temperature, DO, salinity, and pH from surface and bottom locations in the water column. For handling methods requiring shellfish shading after field acquisition, a pre-process shaded shell temperature and pre-process shaded air temperature is required. Additionally, for Delaware Bay oysters that are put on ice immediately, a pre-process meat temperature should be taken.

In order to fully understand what happens along distribution chain to the retailer, we will also be getting samples of oysters from commercial harvesters immediately after harvesting and put on ice or in refrigeration, and will collect samples before the same lot of oyster is shipped when loading into the truck. We will track the lot to its final destination and collect additional sample for analysis. This will be done in conjunction with USFDA. Prior to collection of samples, air temperature and shell temperature will be taken using calibrated hand held meter.

PROJECT DELIVERABLES

The deliverables from this project will be as follows:

1. We will capture air, water and out of water shell temperatures at every sampling location to better understand how this affect presence of pathogenic strains of V.p and V.v
2. Effects of cooling immediately after harvesting using ice chest or refrigerated chamber will also be examined. The levels of total (tlh+) and pathogenic strains (tdh+ and trh+) as well as vvh from samples that were cooled immediately after harvesting will be compared to those stored under a tarp (shaded) at ambient air temperatures for 6-7 hours before processing as well as those refrigerated overnight after left in the shaded air for 6-7 hours. Ambient air temperatures and shell temperatures will be taking prior to sample analysis.
3. This study will provide better understanding of how handling and shipping processes can affect pathogenicity of *Vibrio parahaemolyticus* and *V. vulnificus* before it get to the final consumer.
4. We will serotyped all pathogenic strains isolated during this study to give us the prevalence as well as to better understand if they are temperature dependent.
5. Statistical analysis of the results obtained and recommendations shall be developed and submitted to ISSC.

PROJECT MANAGEMENT APPROACH

The project will be managed as described below:

Project Director: Bruce Friedman, Chief, Bureau of Marine Water Monitoring, will provide the overall management of the project.

Principal Investigator (PI): Robert Schuster, Interim Section Chief, Bureau of Marine Water Monitoring, will manage the data, perform the assessment, and manage the execution of the project.

Field officer: Marc Resciniti will be the lead field officer to collect field data, shellfish, and oversee other field staff needed to perform the study.

Laboratory Technicians: Three Laboratory Technicians will be available to assist in the analysis of samples under the supervision of PI.

DETAILED AND ITEMIZED PRICING

Materials and Supplies

Supplier	Catalog Number	Item	Amt.	Total Cost
VWR	BDH8014	Sodium Chloride	3	$181.47
VWR	90000-744	Nutrient Agar	2	$258.22
VWR	61001-506	Peptone	2	$179.74
VWR	95022-388	TCBS Agar	3	$443.70
VWR	95020-770	CPC Agar	2	$2,039.80
VWR	95057-782	CPC Supplement	2	$168.80
VWR	95060-676	API Kit	1	$1,306.17
VWR	90003-676	Voges-Proskauer A	1	$65.00
VWR	90003-678	Voges-Proskauer B	1	$76.50
VWR	95060-952	TDA Reagent	1	$39.07
VWR	95060-956	NIT 1/NIT 2 Reagent	1	$70.30
VWR	95060-946	Mineral Oil	1	$31.26
VWR	95060-974	James Reagent	1	$39.07
VWR	10052-582	Vibrio Antisera Kit K-Set	1	$6,041.58
VWR	10052-578	Vibrio Antisera Kit O-Set	1	$858.90
VWR	25388-581	50x9mm Tight Fit Plates	2	$308.04
VWR	25384-252	100x15mm Petri Plates	4	$849.52
VWR	12000-806	1uL Inoculating Loops	10	$1,287.90
VWR	12000-814	Inoculating Needles	5	$643.95
VWR	89003-420	100-1,000uL Pipette Tips	4	$582.28

VWR	89092-962	0.1-10uL Pipette Tips	4	$615.80
VWR	53510-012	1-40uL Pipette Tips	1	$175.65
VWR	53510-070	1-100uL Pipette Tips	1	$161.30
VWR	53510-106	1-200uL Pipette Tips	2	$319.48
VWR	33503-136	70% Alcohol Wipes	1	$559.45
VWR	414004-429	Small Latex Gloves	2	$334.60
VWR	414004-430	Medium Latex Gloves	1	$167.30
VWR	21150-478	0.6 mL Amber Microcentrifuge Tubes	1	$39.44
VWR	22179-004	1.5mL Clear Microcentrifuge Tubes	6	$472.68
Life Technologies	10977-015	PCR-Grade Water	1	$29.00
Life Technologies	10966-034	Platinum Taq Polymerase	10	$4,590.00
Life Technologies	4316034	Custom TaqMan Probe MGBNFQ trh_133-23 –Vic Seq: 5'-AGAAATACAACAATCAAAACTGA-3'	1	$255.00
Life Technologies	4316034	Custom TaqMan Probe MGBNFQ Tdh_269-20_FAM Seq: 5'-TGACATCCTACATGACTGTG-3'	1	$255.00
BioGX	760-0001	VP IAC DNA	1	$550.00
IDT	Custom tl_884F	5'-ACTCAACACAAGAAGAGATCGACAA-3'	1	$8.75
IDT	Custom tl_1091R	5'-GATGAGCGGTTGATGTCCAAA-3'	1	$7.35
IDT	Custom trh_20f	5'-TTGCTTTCAGTTTGCTATTGGCT-3'	1	$8.05
IDT	Custom trh_292R	5'-TGTTTACCGTCATATAGGCGCTT-3'	1	$8.05
IDT	Custom tdh_89F	5'-TCCCTTTTCCTGCCCCC-3'	1	$5.95
IDT	Custom tdh_321R	5'-CGCTGCCATTGTATAGTCTTTATC-3'	1	$8.40
IDT	Custom IAC_46F	5'-GACATCGATATGGGTGCCG-3'	1	$6.65
IDT	Custom IAC_186R	5'-CGAGACGATGCAGCCATTC-3'	1	$6.65
IDT	Custom vvhF	5'-TGTTTATGGTGAGAACGGTGACA-3'	1	$8.05
IDT	Custom vvhR	5'-TTCTTTATCTAGGCCCCAAACTTG-3'	1	$8.40

IDT	Custom IAC_109	5Cy5'-TCTCATGCGTCTCCCTGGTGAATGTG-3'-BHQ_2	1	$315.00
IDT	Custom vvh Probe	56-FAM-5'-CCGTTAACCGAACCACCCGCAA-3'-BHQ_2	1	$195.00
IDT	Custom tl_1043	56-JOEN-5'CGCTCGCGTTCACGAAACCGT-3'-BHQ_2	1	$420.00
		Total Costs		$24,419.32

*Cost does not include shipping and handling.

APPENDIX: REFRENCES

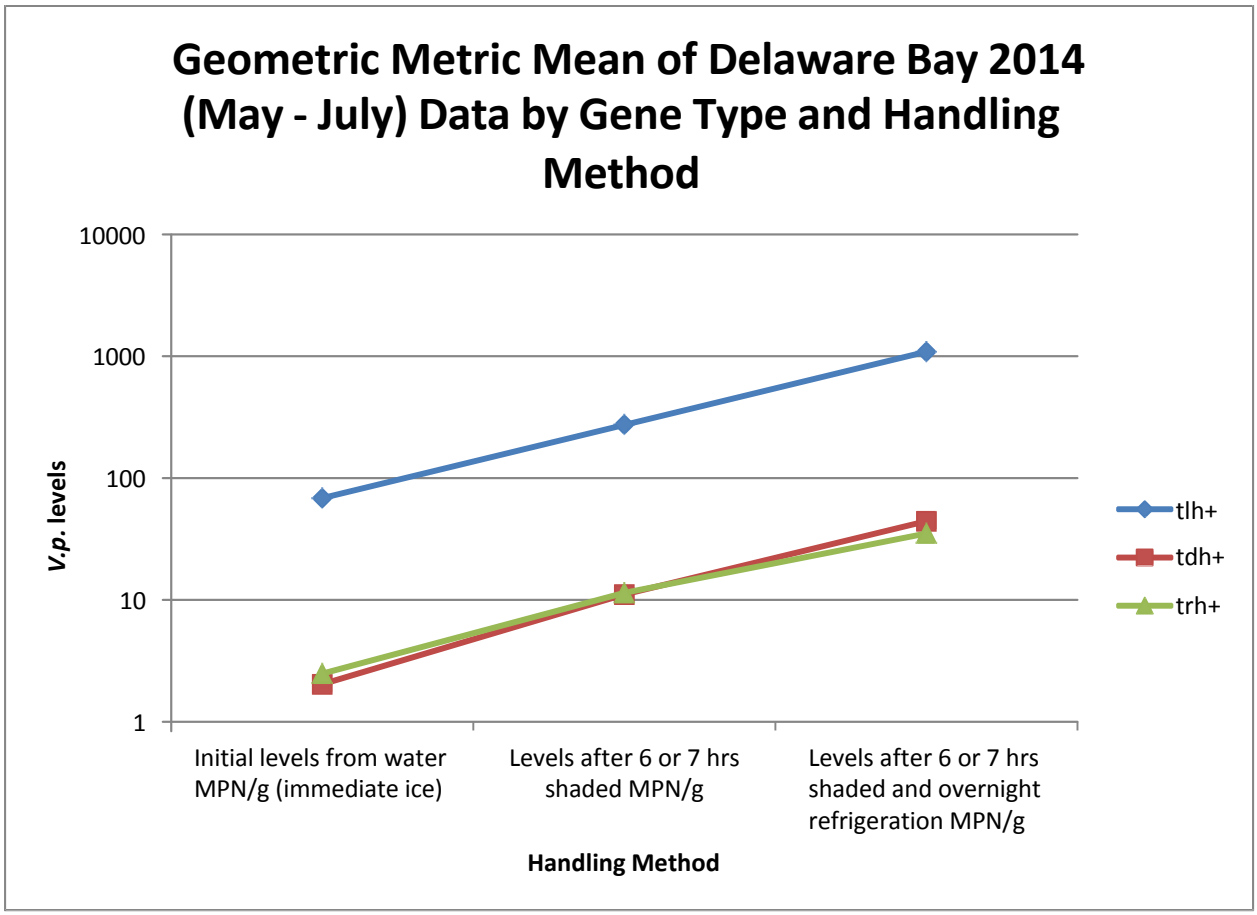
As part of our Vibrio sampling and monitoring plan, the Bureau of Marine Water Monitoring has been studying the relationship between water, air and out of water shell temperatures and pathogenic strains of *V.p.* for the past three years. We also mimic three handling methods:

a. Immediate cooling on ice after harvesting before analysis
b. Shading of oysters for 6-7 hours before analysis;
c. Shading of oysters for 6-7 hours and refrigerated overnight before analysis.

Our preliminary results showed that the level of pathogenic strains (tdh+ and tlh+) from samples that were put on ice immediately after harvesting were little to none. We noticed an increase of these genes from oysters that were shaded for 6-7 hours while the levels either increased or remained constant for the overnight refrigerated samples.

2014 Delaware Bay *V.p.* Sample Results (Preliminary)

	Date	Initial levels from water MPN/g	Levels after 6 hrs shaded MPN/g	Levels after 7 hrs shaded MPN/g	Levels after 6 or 7 hrs shaded and overnight refrigeration MPN/g
tlh+	5/12/2014	<3		0.92	0.92
tdh+	5/12/2014	<3		0.36	0.92
trh+	5/12/2014	<3		0.36	0.92
tlh+	5/19/2014	9.3		4.3	15
tdh+	5/19/2014	4.3		0.74	9.3
trh+	5/19/2014	1.5		1.5	7.5
tlh+	5/28/2014	93		210	2400
tdh+	5/28/2014	0.36		11	2.3
trh+	5/28/2014	9.3		15	14
tlh+	6/2/2014	200		1500	1500
tdh+	6/2/2014	<3		<3	<3
trh+	6/2/2014	0.3		<3	<3
tlh+	6/9/2014	93		93	15,000
tdh+	6/9/2014	3.6		43	15,000
trh+	6/9/2014	7.4		43	9,300
tlh+	6/16/2014	43		75	1,500
tdh+	6/16/2014	<0.3		15	430
trh+	6/16/2014	<0.3		15	230
tlh+	6/23/2014	240		2,900	4,300
tdh+	6/23/2014	<3		43	43
trh+	6/23/2014	3.6		43	43
tlh+	6/30/2014	240		24,000	4,300
tdh+	6/30/2014	<3		120	210
trh+	6/30/2014	<3		110	210
tlh+	7/7/2014	21	4,300		15,000
tdh+	7/7/2014	<3	43		93
trh+	7/7/2014	3.6	23		23
tlh+	7/14/2014	930	930		7,500
tdh+	7/14/2014	3.6	23		93
trh+	7/14/2014	9.2	23		23


Geometric Metric Mean of Delaware Bay 2014 (May - July) Data by Gene Type and Handling Method
10000
1000
100
10
1
V.p. levels
Initial levels from water MPN/g (immediate ice)
Levels after 6 or 7 hrs shaded MPN/g
Levels after 6 or 7 hrs shaded and overnight refrigeration MPN/g
Handling Method
tlh+
tdh+
trh+

APPENDIX: PROJECT TEAM STAFFING

Management Personnel:

1. Bruce Friedman, Chief
   Bruce Friedman has been with the New Jersey Department of Environmental Protection for 26 years. He has extensive experience with Water Enforcement and Compliance and NJPDES Permitting. Bruce helped develop, implement and manage USEPA's Phase II stormwater program in New Jersey, regulating the discharge of stormwater from municipal separate storm sewers. He currently manages NJDEP's Leeds Point Laboratories. He has been involved in source track down and restoration efforts within the Wreck Pond Watershed. Bruce is a graduate of Stockton State College with a Bachelor of Science Degree in Environmental Studies and is a member of New Jersey's Water Monitoring Council, Barnegat Bay Science and Technical Advisory Committee, Interstate Environmental Commission, Interstate Shellfish Sanitation Conference, and the Wreck Pond Watershed Committee.

2. Robert Schuster, Interim Section Chief
   Robert holds a Bachelor of Science Degree in Chemistry with 24 years of experience in both the Chemical and Bacteriological analyses in Marine waters, for the NSSP, USEPA ambient monitoring programs, and the implementation of new technologies, which includes real-time water quality data from buoys, and the development of New Jersey's program for aircraft remote sensing of chlorophyll *a*. He is currently in charge of the laboratory, assessment, and field sections of the NJDEP's Bureau of Marine Water Monitoring.

Laboratory Personnel:

1. Abolade Oyelade – Research Scientist 3.
   Abolade holds Master's degree in Microbiology with over 14 years' experience in research and teaching. He is currently in charge of Advanced Microbiology Laboratory that oversees Vibrio analysis using Multiplex Real-Time PCR Assay as well as Direct Plating Techniques.
2. Elena Heller – Environmental Specialist 3
   Elena holds Bachelor of Arts degree in Environmental Science with over 24 years' experience in performing special projects involving bacteriological analyses of shellfish and marine waters.
3. Carrie Lloyd – Environmental Specialist 2
   Carrie holds Bachelor's Degree in Biology with over 9 year experience at NJDEP Bureau of Marine water monitoring. Techniques and skills acquired during time of employment are membrane filtration, multiple tube analysis, qPCR analysis, direct plating analysis, and other basic laboratory skills such as media preparation and

quality assurance.

4. Eric Feerst – Section Chief (Retired)
   Eric has Bachelor's Degree in Biology with 37 years' experience in Shellfish sanitation, lab methods, Vibrio monitoring. Presently he is a part-time consultant in Vibrio monitoring program.

Field Personnel:

1. Marc Resciniti – Captain State Boat
   Marc has a Bachelor of Science Degree in Environmental Science with 10 years' experience in fisheries sampling and management, and 4 years' experience with the collection of shellfish and water samples for the Bureau's NSSP compliance.
2. Rodney Sloan – Captain State Boat
   Rodney has 4 years of experience with the collection of shellfish and water samples for the Bureau's NSSP compliance.
3. Lonnie LeVance- Captain State Boat
   Lonnie has 2 years of experience with the collection of shellfish and water samples for the Bureau's NSSP compliance.
4. Keith Murphy - Captain State Boat
   Keith has 12 years of experience with the collection of shellfish and water samples for the Bureau's NSSP compliance.
5. Ken Hayek – Principal Environmental Technician
   Ken has 17 years of experience with the collection of shellfish and water samples for the Bureau's NSSP compliance, and water quality sampling techniques for EPA Ambient monitoring projects.
6. Rich Rand- Principal Environmental Technician
   Rich has 15 years of experience with the collection of shellfish and water samples for the Bureau's NSSP compliance, and water quality sampling techniques for EPA Ambient monitoring projects.

CONTRACT

Between

Interstate Shellfish Sanitation Conference
and
Connecticut Department of Agriculture
Bureau of Aquaculture

This Contract shall be effective from October 1, 2014 to August 31, 2015, between the Interstate Shellfish Sanitation Conference, (hereinafter referred to as ISSC) and the Connecticut Department of Agriculture Bureau of Aquaculture (hereinafter referred to as the Contractor).

The parties to this Contract agree as follows:

I. SCOPE OF WORK

Identify and evaluate the effectiveness of techniques and practices that could potentially reduce the risk of Vibrio illnesses. The study will offer viable control options for the shellfish industry that will reduce risk of Vibrio illnesses. The study will consider issues associated with the effects of water temperature on initial levels at harvest and the effects of post-harvest temperature control as a means of reducing risk of illness. The detail of this work is in the Proposal which is a part of this Contract.

II. TIME OF PERFORMANCE

This Contract shall be effective from October 1, 2014 and reported on by August 31, 2015. A final report shall be submitted within thirty (30) days of the end of the contract period.

III. COMPENSATION

The total amount of the contract shall be Twenty One Thousand Six Hundred Seventy Six and 08/100 ($21,676.08) dollars.

IV. METHOD OF PAYMENT

The initial payment shall be for one-half of the contractual amount. The balance is payable upon completion of the contract and the submission of an acceptable final report.

V. TERMS AND CONDITIONS

A. The Contractor shall agree to make positive efforts to utilize the services and products of small and minority owned businesses and individuals where applicable.

B. Any changes to this Contract, which are mutually agreed upon between ISSC and the Contractor shall be incorporated in written amendments to this Contract.

C. The Contractor shall maintain and retain all records and other documents relating to this Contract for a period of twenty-four (24 months from the date of final payment under the Contract, and shall make the documents available for inspection and audit by authorized ISSC and Federal officials.

D. No person shall be excluded from participation, be denied the benefits of, or be subjected to discrimination in relation to any activities carried out under this Contract on the grounds of race, color, sex, religion or national origin.

E. All project deliverables included on Page 9 of 25 of Connecticut Department of Agriculture Bureau of Aquaculture proposal (attached) shall be completed. In the event all deliverables are not fully rendered as provided for in the Contract, any monies which have been paid by the agency under the Contract must be refunded to ISSC.

F. The contractor will submit a progress report no later than June 15, 2015. This progress report shall be a summary of activities completed (a brief summary of no more than two (2) pages).

G. Notwithstanding any other provisions of the Contract, the parties hereto agree that the charges to ISSC by the Contractor are payable from federal grant monies. In the event sufficient grant monies are not made available to ISSC to pay the charges hereunder, this contract shall terminate without further obligation of ISSC. In such event, the ISSC shall certify to the Contractor the fact that sufficient funds are not available to ISSC to meet the obligations of the Contract and such written certification shall be conclusive upon the parties.

H. The Contractor certifies that he/she shall not engage in the unlawful manufacture, distribution, dispensation, possession or use of a controlled substance in the performance of this Contract. This certification also applies to any individual employed by the Contractor.

I. The performance of work under this contract may be terminated by the Executive Director, ISSC, in accordance with this clause whenever he shall determine that such termination is in the best interest of the ISSC. The ISSC shall pay all reasonable costs associated with this Contract that the Contractor has incurred up to the date of

termination of the contract. Two (2) weeks advance notice of the Contract termination will be provided by the Executive Director, ISSC. Either party may terminate this Contract by giving written notice at least 14 days prior to the effective date of such termination.

J. All records, documents, and reports developed in the performance of this contract shall be the property of and available to the ISSC for its use without payment of royalty or additional cost and shall not be subject of an application for a copyright by, or on behalf of, the contracted Contractor.

VI. The Contractor shall deliver to the ISSC, on or before the final date of this Contract, one electronic copy (Microsoft Word) and three hard copies of the final report.

The parties to this Contract hereby agree to any and all provisions as stipulated above.

AS TO ISSC	AS TO THE CONTRACTOR
BY:_____	BY:_____
TITLE:_____	TITLE:_____
DATE:_____	DATE:_____
WITNESSES:	WITNESSES:
_____	_____
_____	_____
MAILING ADDRESS:	MAILING ADDRESS:
209-2 Dawson Road Columbia, SC 29223-1740	_____ _____
EMPLOYER ID#:	EMPLOYER ID#:
52-1656630	_____

Techniques and Practices for Vibrio Reduction Proposal
State of Connecticut Department of Agriculture Bureau of Aquaculture

1. Executive Summary

During the summers of 2012 and 2013, *V. parahaemolyticus* infections of a strain previously traced only to the Pacific Northwest were associated with consumption of oysters and other shellfish from several Atlantic Coast harvest areas[i]. These outbreaks were caused by elevated levels of the naturally occurring bacteria *Vibrio parahaemolyticus* in shellfish. This marine bacterium occurs naturally in brackish and salt-water environments, and may be found in higher concentrations from April through October when coastal waters are warm. Consumers may be exposed to these pathogenic, or disease-causing, bacteria by eating raw or undercooked shellfish, including oysters, clams, lobster, and crab.

Connecticut growing waters were the source of at least 23 confirmed cases of *Vibrio parahaemolyticus* during the summer of 2013, with another additional 15 cases potentially linked to Connecticut waters.

Environmental monitoring for *Vibrio parahaemolyticus* bacteria in Connecticut shellfish has been limited in previous years by federal and state laboratory and resource constraints. In 2013, the Connecticut Department of Agriculture Bureau of Aquaculture (DA/BA) acquired qPCR technology (Life Technologies 7500 Fast Real Time PCR System) which will allow the DA/BA in their role as the State Shellfish Authority to conduct environmental monitoring for total *V.p.*, tdh+ and trh+ indicators at a statewide scale.

In order to gain a better understanding of *Vibrio parahaemolyticus* levels and their relevance to implementing meaningful Vibrio controls in Connecticut growing waters, the 2014 DA/BA monitoring plan includes the collection of environmental parameters such as water temperature, air temperature, salinity and depth that may correlate to levels of Vibrio bacteria in shellfish. In addition, post-harvest time and temperature controls currently in place as required by the Connecticut 2014 *Vibrio parahaemolyticus* Control Plans will be evaluated by using continuous temperature data loggers (ACR Smart Button) to determine the effectiveness of post-harvest temperature controls and correlate these controls to quantifiable impacts on Vibrio levels.

Real time Vibrio monitoring and continuous environmental observations will be used to inform our understanding of the temporal variability and spatial distribution of *V.p.* in LIS growing areas. This data may provide an early warning system and allow the DA/BA to proactively manage risk of illness by limiting harvest from specific locations or requiring more stringent controls under certain environmental conditions.

In addition, with the assistance of collaborating research partners at the University of Connecticut's Department of Marine Sciences, this proposed ISSC project will analyze previously collected and ongoing observations to establish how *V.p.* levels vary with LIS environmental conditions. The existing FDA model, "Quantitative Risk Assessment on the Public Health Impact of Pathogenic *Vibrio parahaemolyticus* in Raw Oysters" (4) will be used to tailor the pre-harvest component of the model to the LIS using the analyzed observations and apply it for retrospective analysis and forecasts.

As requested by the ISSC RFP, this study will evaluate the effectiveness of a variety of post-harvest practices that could potentially reduce the risk of Vibrio illnesses. One of the major components of this work will be the field evaluation of control options for the shellfish industry that would reduce risk of Vibrio illnesses.

Proactive pre-harvest controls, such as identification of lower risk harvest areas, limiting harvest under specific environmental conditions, or applying specific controls under certain environmental controls will also be evaluated in terms of the effectiveness of the actions on limiting Vibrio growth.

This research team has the ability to initiate data gathering by August 2014 as the DA/BA has been actively involved in data collection and Vibrio monitoring since June of 2014.

This work will complement research being proposed by Co-PIs Whitney (UCONN), Ward (UCONN), and DeRosia-Banick (DA/BA) for Connecticut Sea Grant RFP for the 2014-2016 funding cycle *Modeling Vibrio parahaemolyticus Outbreaks in Commercial Shellfish Areas in Western Long Island Sound: Research Linking Local Environmental Factors and Uptake by Oyster.*

The chief project **objectives** are to:

- Evaluate post-harvest time and temperature controls currently in place as required by the Connecticut 2014 *Vibrio parahaemolyticus* Control Plans using continuous temperature data loggers (ACR Smart Button) to determine the effectiveness of post-harvest temperature controls and quantify how these controls impact Vibrio levels
- Collect and analyze Vibrio bacteria levels (total *V.p.*, tdh+ and trh+) from growing areas throughout Long Island Sound, with a focus on the Norwalk/Westport outbreak areas
- Collect and analyze environmental data including water temperatures, air temperatures, salinity, depth in order to apply FDA Vibrio Risk Assessment model to Connecticut environmental data and Vibrio monitoring data
- Work with stakeholders, managers, and scientists at the state, regional, and national level to:
  1) translate this research into viable harvest and control options for the shellfish industry that would reduce risk of Vibrio illnesses;
  2) to assess regional and environmental differences that may better define the combination(s) of post-harvest time and temperature controls that will be most effective for a given region or state and;
  3) ensure that the results of these research efforts will be fully considered by the membership of the ISSC.

2. Approach and Methodology

The research will test the following **hypotheses**:

- Shellfish in deeper offshore growing areas have consistently lower *V.p.* levels than nearshore areas due to lower near-bottom temperatures. These are less like to require *V.p.*-related closures.
- Post-harvest controls, such as rapid cooling of oysters to 50°F within 1 hour of harvest, will reduce the proliferation of Vibrio bacteria and associated risk of illness associated with Connecticut oysters
- A linear regression model (following FDA methods) linking the logarithm of *V.p.* counts in shellfish to water temperature and salinity values supplied by a hydrodynamic model will show statistically significant agreement with observations in LIS growing areas.

The project will combine observations, models, and laboratory experiments to answer the research question for the 2014-2015 period and inform *V.p.* management efforts.

The specific tasks for the observational and laboratory efforts are described in the Methodological Approach section.

Field Observations:

Long Island Sound Environmental Data:

Beginning in June of 2014, DA/BA deployed 16 HOBO Water Temp Pro v2 temperature data loggers at near- bottom depth (Onset Corp) and six DST conductivity, temperature, and depth (CTD) data loggers have been deployed at near-surface and near-bottom depth at 3 locations in Westport and Milford (Star-Oddi) (Figure 1). Vantage Pro 2 remote weather stations (Davis) have been purchased and will be deployed in Norwalk and in Milford to collect meteorological conditions, including rainfall and air temperature as close to the growing area as possible.

Additional environmental data to be collected via the ISSC funding will include near-surface temperature data at locations where near-bottom temperatures are being collected (16 additional Hobo Water Temp Pro v2), conductivity/temperature loggers for additional continuous salinity measurements (6 Hobo Temperature and Conductivity Data Loggers), and GPS located temperature, salinity and depth profiles at the time of oyster sample collection (YSI CastAway). See attached budget for equipment being requested in support of this proposal.

Station locations have been identified to provide spatial coverage throughout Connecticut growing waters that are actively in use for oyster cultivation. A higher intensity of data collection is focused on the waters of Norwalk and Westport, where the majority of oysters associated with the 2013 *Vibrio parahaemolyticus* outbreak were harvested.

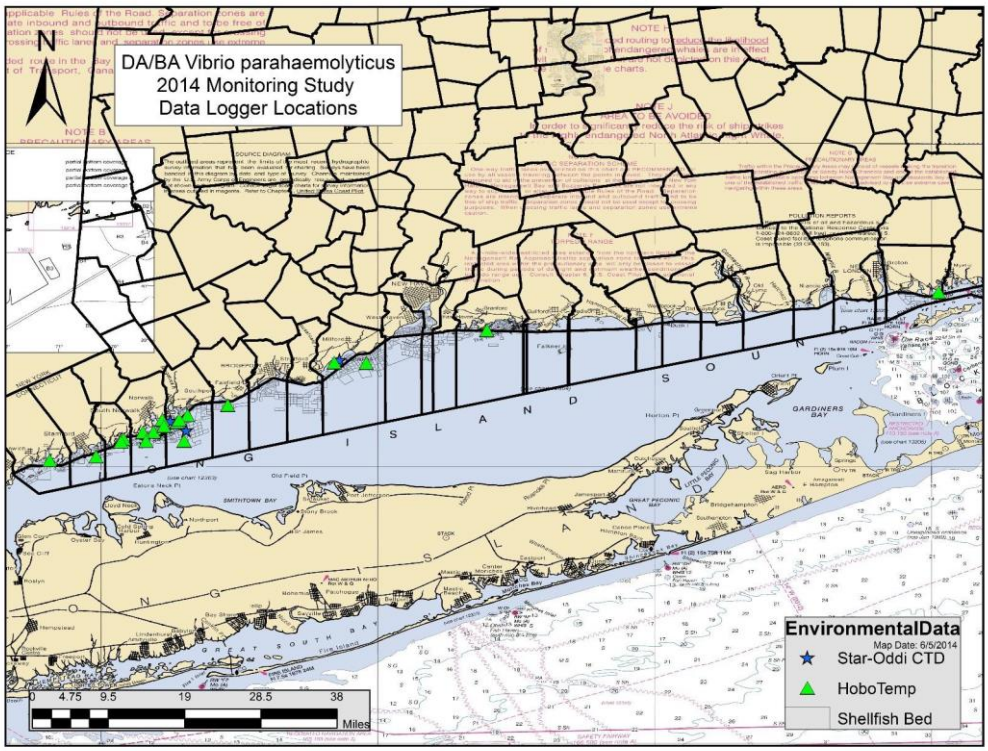


Figure 1. 2014 Vibrio parahemolyticus environmental data monitoring locations.

In addition, SmartButton (ACR Systems) continuous temperature data loggers are being deployed to collect data and evaluate the effectiveness of post-harvest controls on shellfish temperatures and Vibrio levels.

Funding to purchase an additional 25 SmartButton loggers is being requested via this ISSC proposal to support expanded data collection to evaluate post-harvest controls.

***Vibrio parahaemolyticus* Monitoring Data:**

From June 15 to October 31, 2014, and June 1 through October 31, 2015, 16 shellstock samples will be collected on a bi- weekly basis by DA/BA staff and analyzed using a for total *V.p.*, tdh+, and trh+ levels (Figure 2. 2014 Vibrio parahaemolyticus sample collection locations. Samples will be analyzed for Total Vibrio parahaemolyticus, tdh+, and trh+ levels.). More intensive sampling will be focused on the Westport/Norwalk inner island waters that were associated with the 2013 outbreak, as well as the offshore waters in these towns.

Shellfish samples will be analyzed for total *Vibrio* parahaemoloyticus using MPN-real-time PCR (MPN-Rti-PCR) as previously described by Jones et al (5). A second multiplex Rti-PCR method targeting the *tdh* and *trh* genes, with an internal amplification control (IAC) will be used for identification of pathogenic *V. parahaemolyticus as described by* Jones and Lüdeke (6).

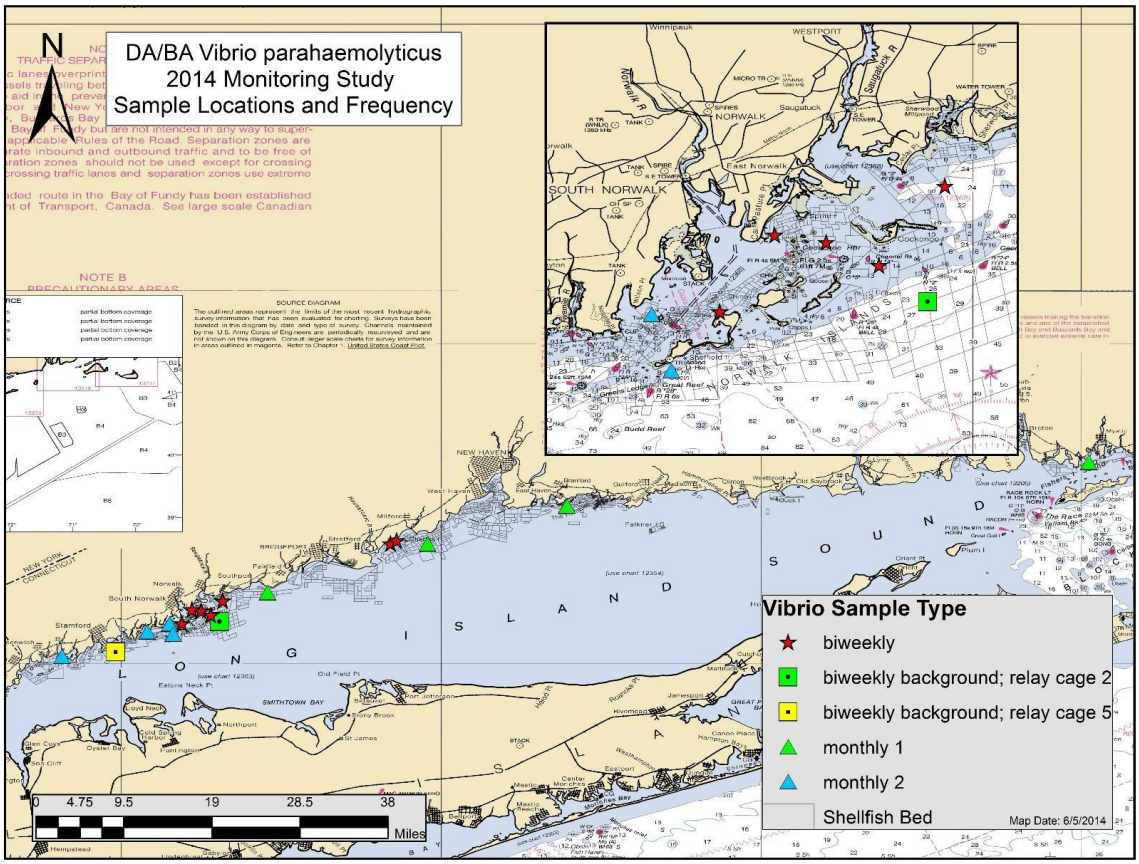


Figure 2. 2014 Vibrio parahaemolyticus sample collection locations. Samples will be analyzed for Total Vibrio parahaemolyticus, tdh+, and trh+ levels.

On a rotating basis, 2 of the 16 samples biweekly will be dedicated to investigating the impacts of the various post- harvest temperature controls on Vibrio levels. Connecticut will have several different Vibrio control plans in place during 2014; the general CT VPCP which allows 5 hours from harvest to refrigeration and 5 hours to an internal temperature of 50°F, as well as rapid cooling to internal temperature of 50°F using either ice or mechanical refrigeration. As this research is implemented during 2014 and 2015, a number of different Vp controls may be in effect depending on how the season progresses, and this portion of the study will be conducted in order to gain the most useful information in terms of how successful these various controls are in terms of limiting the proliferation of Vibrio bacteria.

Modeling:

V.p. modeling follows the approach described in Appendix 5 of the FDA Risk & Safety Assessment (ref???) (**Administration**, 2005) relating the base-10 logarithm of Vp count per gram sample tissue (Vp count) to water temperature in Celsius (T) and salinity in psu (S) and an error term (ε):

$$l\diamond g_{10}(V\diamond c\diamond\diamond\diamond\diamond) = \diamond + \diamond\diamond + \diamond_1\diamond + \diamond_2\diamond^2 + \varepsilon$$

The coefficients in the preceding equation (α, β, γ_1, γ_2) and the standard deviation (σ) of the random normal error from
the fit are estimated using a Tobit regression model. Table YYY includes regression coefficients and errors based on three studies including in the FDA Risk & Safety Assessment.

Table 1. Regression coefficients and error standard deviation for *V.p.* model equation

Study	**α**	**β**	**γ_1**	**γ_2**	**σ**
DePaola et al, 1990	-2.63	0.12	0.18	-0.0042	1.00
FDA/ISSC, 2001	-2.05	0.10	0.20	-0.0055	0.73
Washington DOH, 2000, 2001	-1.02	0.30	-0.39	0.0084	0.87

Even though the salinity coefficient is larger than the temperature coefficient, the FDA operational *V.p.* model currently excludes the salinity dependence. For the proposed project the salinity dependence will be included because the data are available and freshwater plumes entering western LIS (e.g Housatonic and Norwalk) create salinity variations in time and space.

3. Project Deliverables

***Vibrio parahaemolyticus* Analysis (Total *V.p.*, tdh+ and trh+)**

Sample Dates (week of)	Process Study Sample #	Environmental Monitoring Sample #	Environmental Data Collection
10/06/14		8	
10/20/14		8	Pull Hobos
05/18/15			Deploy Hobos
05/25/15			Deploy Shellfish Cages
06/01/15	8	8	
06/15/15	8	8	
06/22/15			Offload Hobo Data
06/29/15	8	8	
07/06/15			Cage Maintenance
07/13/15	8	8	
07/20/15			Offload Hobo Data
07/27/15	8	8	
08/03/15			Cage Maintenance
08/10/15	8	8	
08/17/15			Offload Hobo Data
08/24/15	8	8	
08/31/15			Cage Maintenance
09/07/15	8	8	
09/14/15			Offload Hobo Data
09/21/15	8	8	
09/28/15			Cage Maintenance
10/05/15	8	8	
10/12/15			Offload Hobo Data
10/19/15	8	8	
10/26/15			Pull Hobos and Cages
Total ISSC Samples (October 1, 2014 through August 31, 2015)	**56**	**72**	

Key Project Deliverables include:

- Informing improved regional understanding of how environmental factors such as water temperature, air temperature, depth, and salinity correlate to total *V.p.*, tdh+, and trh+ levels and making these results available to regional and national partners via a webinar presentation sharing the Connecticut findings;
- Determining the impact of post-harvest time and temperature controls on the proliferation of total and pathogenic *V.p.* and using this data to identify controls that are most effective for Connecticut and the Northeast Region and making these results available to regional and national partners via a webinar presentation sharing the Connecticut findings;

- Translating this research into viable harvest and control options for the shellfish industry that would reduce risk of Vibrio illnesses and sharing this information with industry via a webinar or in-person presentation.

4. Project Management Approach

Project results will be translated into state, regional and national management tools through cooperation with the Connecticut Department of Agriculture Bureau of Aquaculture, National Oceanic and Atmospheric Administration, US Food and Drug Administration, Interstate Shellfish Sanitation Conference, and State Shellfish Authorities and shellfish industry members in the Northeast Region. This task will be conducted with the target audience of state shellfish authorities, FDA regional shellfish specialists, environmental managers and scientists via conference calls and meetings discussing research plans and results throughout the project on a quarterly basis.

An initial conference call occurred during 2014 and guided this proposal development as well as the Connecticut Sea Grant proposal.

Environmental and vibrio data collected and generated by DeRosia-Banick and DeCrescenzo will be shared with collaborating researchers via email updates of data in Excel spreadsheet form along with GIS shapefiles or latitiude and longitude correlating to data collection locations to facilitate modeling.

Conference calls between collaborative partners FDA, and the appropriate committees of the ISSC will be scheduled on a quarterly basis in order update interested parties on research progress. Deliverables generated may be disseminated amongst managers and stakeholders prior to the end of project as deemed appropriate by the group.

5. Detailed and Itemized Pricing

Total Match CT Department of Agriculture Commitment: $32,560

Analyst Hourly Rate (includes benefits):
Salary: $45.00/hour
Time match: 272 hours* $45/hour = $ 12,240 over the 2 year period
Boat Captain Hourly Rate (includes benefits):
Salary: $55.00/hour
Time match: 192 hours* $55/hour = $10,560 over the 2 year period
Microbiologist Hourly Rate (includes benefits):
Salary: $45.00/hour
Time match: 80 hours* $45/hour = $3600 over the 2 year period
Boat Fuel: 7 gal/hr * $5/gal = $35/hour fuel
176 hours * $35 per hour = $6160

Funding Requested:

Item	Supplier	Item #	Quantity	Unit	Total Price
PCR Freezer Paks	Fisher Scientific	5115-0032	2	152.02	304.04
Mini-Centrifuge	Fisher Scientific	S67601B	1	276.25	276.25
Dry Block Heater	Fisher Scientific	07-201-839	1	689.85	689.85
Pipet tips 0.1-10	Fisher Scientific	02-707-439	1 pack	41.66	41.66
Pipet tips 2-10	Fisher Scientific	02-707-432	1 pack	41.66	41.66
Pipet tips 20-200	Fisher Scientific	02-707-430	1 pack	41.66	41.66
Tube racks 1.5ml	Fisher Scientific	14-810-31	4 cases	98.67	394.68
Tube racks 2.0ml	Fisher Scientific	05-541	1 cases	119.92	119.92
Rnase away	Fisher Scientific	14-375-35	1	71.84	71.84
2 ml Tubes	Fisher Scientific	02-682-558	1 pack	43.68	43.68
Block well 24 (1.5ml)	Fisher Scientific	07-201-842	2	84.50	169.00
Block well 24 (2ml)	Fisher Scientific	07-201-840	2	84.71	169.42
Pipet tips 100-1000	Fisher Scientific	02-707-404	1	41.66	41.66
Micro tubes black	Fisher Scientific	03-391-161	1	32.09	32.09
Micro tubes 1.5ml	Fisher Scientific	05-408-131	4	24.16	96.64
Hobo Temperature and Conductivity Data	Onset	U24-002-C	6	750.00	4,500.00
HOBO Water Temperature Pro v2	Onset	U22-001	20	129.00	2,580.00
SmartButton (25-Pack)	ACR Systems	01-0185	2	1,245.00	2,490.00
CastAway CTD-YSI	Interactiv Oceanographics	400000	1	5,515.00	5,515.00
ultra-pure	life tech	500 ml	1	29.00	29.00
ROX Dye	life tech	500ul	1	41.60	41.60
platinum DNA Polymerse	life tech	120 reactions	2	99.00	198.00
HAC	IDT	100 Nm	1	315.00	315.00
TL-1043	IDT	250 NM	1	420.00	420.00
TL-884F	IDT	100 NM	1	13.75	13.75
TL-1091R	IDT	100NM	1	11.55	11.55
TRH 20 F	IDT	100 NM	1	12.65	12.65
iac-186r	IDT	100NM	1	10.45	10.45
trh292r	IDT	100 nm	1	12.65	12.65
tdh 89f	IDT	100 nm	1	9.35	9.35
tdh 321r	IDT	100 nm	1	13.20	13.20
iac46f	IDT	100nm	1	10.45	10.45
PCR Nuc Mix	Roche		1	328.00	328.00
VP-IAC	BioGX		1	500.00	500.00
Custom TAQMAN	Life Tech	vic	1	153.00	153.00
Custom TAQMAN	Life Tech	Fam	1	153.00	153.00
platinum Tac	Life Tech	600 reactiuons	1	459.00	459.00
T Buffer	Fisher	4 liters	1	244.38	244.38
Micro 8 tube strip	Life Tech	1000 tubes	2	102.00	204.00
adhesive film	Life Tech	100 covers	2	219.00	438.00
96 well plate	Life Tech	20 plates	2	134.00	268.00
8 cap strips	Life Tech	300 strips	2	106.00	212.00
				Total Funding Requested	21,676.08

6. Appendix: References

1. Scallan E, Hoekstra RM, Angulo FJ, et al. Foodborne illness acquired in the United States—major pathogens. Emerg Infect Dis 2011;17:7–15.
2. Martinez-Urtaza J, Baker-Austin C, Jones JL, Newton AE, Gonzalez-Aviles GD, DePaola A. Spread of Pacific Northwest *Vibrio parahaemolyticus* strain. N Engl J Med 2013;369:1573–4.
3. CDC. Increase in *Vibrio parahaemolyticus* illnesses associated with consumption of shellfish from several Atlantic coast harvest areas, United States, 2013. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/vibrio/investigations/index.html
4. USFDA. Quantitative Risk Assessment on the Public Health Impact of Pathogenic Vibrio parahaemolyticus in Raw Oysters, Unites States, 2005.
5. Jones, J. L., Y. Hara-Kudo, J. A. Krantz, R. A. Benner, Jr., A. B. Smith, T. R. Dambaugh, J. C. Bowers, and A. DePaola. 2012. Comparison of molecular detection methods for *Vibrio parahaemolyticus* and *Vibrio vulnificus*. Food Microbiol. 30:105-111.
6. Jones, J. L. and Lüdeke, C. H. M. 2012. Improved Detection of Pathogenic *Vibrio parahaemolyticus* from Oyster, Water, and Sediment Using Real-Time PCR. Final Program 112th Gen. Meet. Am. Soc. Microbiol. American Society for Microbiology, Washington, DC.

7. Appendix: Project Team Staffing

Kristin DeRosia-Banick (Co-PI) Environmental Analyst II Connecticut Department of Agriculture Bureau of Aquaculture	190 Rogers Avenue Milford, CT 06460 Kristin.DeRosia-Banick@ct.gov 203-874-0696 ext 112
Joseph DeCrescenzo (Co-PI) Microbiologist II Connecticut Department of Agriculture Bureau of Aquaculture	190 Rogers Avenue Milford, CT 06460 Joseph.DeCrescenzo@ct.gov 203-874-0696 ext 112
Michael M. Whitney (collaborating researcher) Associate Professor Department of Marine Sciences University of Connecticut	1080 Shennecossett Road Groton, CT Michael.whitney@uconn.edu 860-405-9157
Evan Ward (collaborating researcher) Professor Department of Marine Sciences University of Connecticut	1080 Shennecossett Road Groton, CT Evan.Ward@uconn.edu 860-405-9073

See attached Curriculum vitae for investigators and collaborators on this proposal.

8. Appendix: Company Overview

9. Appndix: Background ISSC Proposal 13-204

Proposal 13-204 was recommended for adoption by the 2013 Task Force II. FDA concurred with Conference action on Proposal 13-204 with the following comments and recommendations.

- FDA urges the ISSC to consider that the evidence most needed for determining the public health

benefit of various control strategies would be to compare Vibrio levels at harvest to levels achieved with currently implemented time to temperature control measures and levels achieved using various other control strategies, including immediate cooling.

- To expand further, a more comprehensive approach could examine changes in Vibrio levels as half shell product moves from harvest through processing and distribution.
- These data could inform allocation of regulatory resources to achieve the greatest public health benefit.

Efforts outlined above are intended to help improve existing Vibrio controls, identify additional approaches for reducing risk and improve the effectiveness of the National Shellfish Sanitation Program (NSSP).

ISSC has been allocated $75,000 by the FDA and is seeking to fund multiple studies to identify and evaluate the effectiveness of techniques and practices that could potentially reduce the risk of Vibrio illnesses. The purpose of the RFP is to invite qualified entities to propose studies that could offer viable control options for the shellfish industry that would reduce risk of Vibrio illnesses.

***Vibrio parahaemolyticus* Illnesses in Connecticut**

(excerpted from FDA's FY 2013 *Vibrio* Risk Management Plan Implementation Program Element Evaluation Report (PEER) for Connecticut)

1. In 2013, Connecticut experienced their first *V.p.* outbreak. That outbreak was associated with oysters harvested from Westport and Norwalk and resulted in a recall of those species harvested from specific lots between July 3 and August 2, 2013. The recall also included clams on a precautionary basis because some of the 2013 illnesses involved both clam and oyster consumption. Thus a mandatory *V.p.* Control Plan for Connecticut will be required to be implemented through the 2018 season unless another *V.p.* outbreak pushes the cut-off date further into the future. No *Vibrio vulnificus* illnesses have been documented as a result of individuals consuming shellstock from the waters of Connecticut.

2. There were no *Vibrio* illness outbreaks associated with CT shellfish in FY12. The DA/BA has investigated or participated in investigations in seven single illness cases of *V.p.* and one single illness case of *Vibrio fluvialis* in FY12 (Table 2). Three *V.p.* illnesses were linked to the Oyster Bay, NY outbreak. Three *V.p.* cases implicated CT oysters; one case was epidemiologically confirmed to be associated with CT oysters. The *V.f.* illness had a multi-state shellstock exposure.

3. As illustrated in Table 2, the number of cases attributed to *Vibrio* has remained steady 2009- 2012. The number of cases epidemiologically linked to CT shellstock remained steady through 2012 when mandatory *V.p.* controls were instituted for oysters in late July and voluntary controls were instituted for clams. However, in 2013 the number of *V.p.* cases numbers jumped significantly.

Table 2. *Vibrio* Illness Investigations in Connecticut 2009 through 2012

Year	Number of Cases	Source States
2009	7 (5 involving CT)	1 MA (clams August) 1 CT or RI (oysters August) 1 CT or NY (clams August) 1 Unknown (oysters September) 3 definitely CT (1 oysters, 1 clams, 1 unknown)
2010	5 (3 involving CT)	1 ME, MD or VA (mussels or oyster August) 1 CT, ME, or WA (oysters August) 1 NY, WA, ME, MA (oysters) 2 definitely CT (1 clams July, 1 clams June)
2011	6 (5 involving CT)	1 CT, PE, NY (clams and oysters August) 1 Unknown (clams August) 3 definitely CT (1 *V.f.* oysters July, 1 *V.f.* and *V.p.* oysters August, 1 clams September) 1 CT or WA
2012	7 (4 involving CT)	1 definitely CT (oysters June) 1 NY or CT (oysters June) 1 MA (oysters May) 1 case NY (clams July) 1 case NY or CT (oysters late May/early June) 1 (CT, NY, ME, MA, PE) *V.f.* confirmed (clams and oysters July) 1 case RI (clams August)

Table 3. Connecticut *Vibrio* Illness Investigations 2013

Traceback Code	Traceback Investigation Conclusion	Number of Cases
1	CT Confirmed to Outbreak/Closure Area	11
2	CT Confirmed (Outbreak/Closure plus other CT)	8
3	CT Confirmed (single source outside of outbreak area)	2
4	Out-of-State Confirmed	7
5	CT Outbreak Plus Out-of-State (with PFGE Match)	4
6	CT Plus Out-of-State (Unconfirmed/NO PFGE Match)	6
7	Unconfirmed case, CT Product	2
8	Recreational Case	3
0	Traceback Pending	0
9	CT Confirmed Multiple Possible Sources Outside Outbreak Area	2
	Total CT Confirmed Cases (Traceback Code 1, 2, 3, 9)	**23**
	CT Outbreak Area (Traceback Code 1 & 2)	**19**
	Total *V.p.* Related	45

4. In general, the CT Department of Public Health (DPH) receives an average of 20 – 25 reports of *Vibrio* infections annually. These reports typically increase in mid-summer and cases are most often related to shellfish consumption or recreational water exposure. When cases are reported to the DPH, the Department of Public Health, Epidemiology and Emerging Infections Program (EEIP) works closely with local health departments (LHDs) to conduct case investigations, utilizing the Cholera and other Vibrio Illness Surveillance Report (COVIS) form issued by the Centers for Disease Control and Prevention (CDC). When seafood consumption is reported by the case, the EEIP notifies the Department of Public Health, Food Protection Program (FPP) for further seafood investigation, as warranted. The FPP will need to follow up with the DA/BA, if warranted. Because Connecticut is a FoodNet site, the EEIP is expected to forward the COVIS report to the CDC within 30 days of the specimen collection date for the case. Therefore, when feasible the DA/BA makes every attempt to complete page 4 of the COVIS form within this 30-day period so it can be included with the initial COVIS form submission to CDC. When this is not feasible, the DA/BA will forward an updated COVIS report to the FPP and/or EEIP for submission to CDC once available.

5. The occurrence of continuing sporadic *Vibrio* illnesses compounded by the 2013 *V.p.* outbreak affects Connecticut's *Vibrio* Management Plan. The occurrence of an outbreak on the New York shore of Long Island Sound, and a single epidemiologically confirmed illness associated with Connecticut oysters, precipitated the precautionary closure of growing area waters, and the implementation of the first mandatory *Vibrio* controls at the harvester/dealer level for oysters in 2012. Additionally, the DA/BA began conducting routine testing of oysters and clams for total and pathogenic *V.p.* levels, instituted voluntary controls at the harvester/dealer level for clams, and increased harvester/dealer education efforts. The *Vibrio* MOAs between the CT DA/BA and oyster harvester/dealers were modified to reflect actual aquaculture operations. In many instances, the modified MOAs were more restrictive than the mandatory 5 hours from harvest to refrigeration requirement established by the DA/BA. The DA/BA collaborated with the harvester/dealers operations on a case-by-case basis and made recommendations that reflected best practices for the individual operation.

Connecticut's 2014 *Vibrio parahaemolyticus* Control Plan (*VPCP*)

In response to the 2013 illness outbreak of *Vibrio parahaemolyticus* illnesses related to Connecticut shellfish harvested from the waters of Norwalk, Westport, and Darien, the DA/BA recommended several different options for mandatory *VPCP* to be implemented at the harvester/dealer level during the 2014 season. Because all illnesses during the 2013 season were associated with these waters, and other harvest areas in Connecticut were not implicated, a more stringent control plan was required for the waters of Norwalk, Westport and Darien. The *VPCP* for these waters requires rapid cooling of oysters on-board the harvest vessel to an internal tissue temperature of 50°F within 1 hour of harvest. The 2014 Connecticut *VPCP* for growing areas outside of the outbreak area requires 5 hours from harvest to refrigeration, and 5 hours to achieve an internal temperature of 50°F.

The DA/BA held an industry meeting on December 13th, 2013 to educate harvesters on the 2013 outbreak and to present the results of the 2014 Vibrio Risk Assessment and the 2014 VPCP requirements. The following recommendations were made in a January 15th, 2014 letter to the industry which were mailed to

all shellfish harvesters licensed in Connecticut along with copies of the two 2014 Vibrio parahaemolyticus Control Plans.

1. The Department is strongly recommending that ***all Connecticut oyster producers*** use an on-board ice slurry method of rapid cooling during the 2014 VPCP control plan months (June 1 through August 31). This method has been proven by FDA to effectively limit the post-harvest growth of Vibrio bacteria, and is our best chance of reducing the risk of illness associated with oysters produced in Connecticut.

2. The Department is **requiring that all oysters harvested from ALL WATERS of Darien, Norwalk, and Westport** be rapidly cooled using an on-board ice slurry method capable of cooling oysters to an internal temperature of 50°F within 1 hour of harvest or time of first exposure. This requirement has been implemented due to the large number of illnesses associated with oysters produced in Darien, Norwalk and Westport. Several illnesses were associated with oysters produced outside of the closure area, and hence this requirement is for all waters in Darien, Norwalk and Westport, rather than limited to the 2013 closure area.

DA/BA followed this letter up with calls to each individual oyster harvest working in the Norwalk, Westport, and Darien growing areas reminding them that they should make an appointment with DA/BA to present their plans for a rapid cooling process, if they planned on harvesting oysters from these waters. The DA/BA collaborated with the harvester/dealers operations on a case-by-case basis and made recommendations that reflected best practices for the individual operation in terms of the rapid cooling process implemented by each of the companies and that were appropriate for the volume and practices of each company. DA/BA expanded rapid cooling approvals to allow direct ice and mechanical refrigeration in addition to ice slurry, if the process was found to be capable of achieving internal temperatures of 50°F within 1 hour of harvest.

During 2014, a number of different rapid cooling processes were approved by the DA/BA in order to reduce oyster temperatures to an internal temperature of 50°F within 1 hour of harvest:

1) Ice slurry processes using large insulated totes into which dredge loads of loose oysters could be placed for large-scale harvest operations
2) Ice slurry processes using large insulated totes into which sorted and bags oysters are placed for cooling and then transferred onto ice for holding
3) Direct ice system into which loose rough sorted oysters are placed for transport back to land-based refrigerated facility for final sorting and bagging
4) On-board mechanical refrigeration into which oysters are placed in totes for rapid cooling and holding for transport back to land-based refrigerated facility for final sorting and bagging.

In addition, in growing areas not required to rapidly cool oysters, the general Connecticut VPCP was also in place which requires harvesters to place oysters under temperature control within 5 hours of harvest, and to reduce internal temperatures to 50°F with 5 hours of harvest.

BIOGRAPHICAL SKETCH

J. Evan Ward University of Connecticut

Professional Preparation:

Memorial University of Newfoundland, Ocean Sciences Center, Canada	Invertebrate Physiology	Post-Doc, 1990-1992
University of Delaware, Delaware	Marine Biology/Biochem.	Ph.D., Dec., 1989
University of Delaware, Delaware	Marine Biology/Biochem.	M.S., June, 1985
Stockton State College, New Jersey	Marine Science/Biology	B.S., June, 1981

Appointments:

Professor, University of Connecticut, Department of Marine Sciences, Groton, CT, 2009 - present
Visiting Scholar, University of Exeter, Department of Biosciences, Exeter, UK, August 2011 - January 2012.
Associate Professor, University of Connecticut, Department of Marine Sciences, Groton, CT, 2003 - 2009 (promoted)
Visiting Professor, University of Panama, Department of Marine Science and Limnology, Republic of Panama, July 2004 - January 2005
Assistant Professor, University of Connecticut, Department of Marine Sciences, Groton, CT, 1997 - 2003 (promoted & awarded tenure)
Assistant Professor, Salisbury State University, Department of Biological Sciences, Environmental Marine Studies Program, Salisbury, MD, 1994 - 1997
Adjunct Research Associate, University of New Brunswick, Department of Biology, Saint John, New Brunswick, Canada, 1992 - 1994

Five Products Relevant to Proposal:

* Pierce , M.L., **J.E. Ward** & F.C. Dobbs, 2014. False positives in Biolog EcoPlates™ and MT2 MicroPlates™ caused by calcium. *J. Microbiolog. Meth*. 97: 20–24.

Allam, B., W.E. Carden, **J.E. Ward**, G. Ralph, S. Winnicki & E. Pales Espinosa, 2013. Early host pathogen interactions in marine bivalves: Evidence that the alveolate parasite *Perkinsus marinus* infects through the oyster mantle during rejection of pseudofeces. J. Invert. Path. 113: 26-34.

* Lyons, M. M., **J. E. Ward**, H. Gaff, R. Hicks, J. Drake & F.C. Dobbs, 2010. Theory of island biogeography on a microscopic scale: Are organic aggregates islands for aquatic pathogens? Aquatic Microbial Ecology, 60: 1–13.
* Lyons, M.M., Y.T. Lau, W.E. Carden, **J.E. Ward**, S.B. Roberts, R.S. Smolowitz, J. Vallino & B. Allam, 2007. Characteristics of marine aggregates in shallow-water ecosystems: Implications for disease ecology. EcoHealth. 4: 406-420.
* Lyons, M.M., **J.E. Ward**, R. Smolowitz, K.R. Uhlinger & R.J. Gast, 2005. Lethal marine snow: Pathogen of bivalve mollusc concealed in marine aggregates. Limnol. & Oceanogr. 50: 1983-1988.
* - students trained in the Ward lab & funded by external grants

Five Other Products:

Shumway, S.E., **J.E. Ward**, E. Heupel, B.A. Holohan, J. Heupel, T. Heupel & D.K. Padilla, 2014. Observations of feeding in the common Atlantic slippersnail *Crepidula fornicata* L., with special reference to the "mucus net." J. Shellfish Res. 33: 1–13.

Wall, C.C., C.J. Gobler, B.J. Peterson & **J.E. Ward**, 2013. Contrasting growth patterns of suspension feeding molluscs (*Mercenaria mercenaria, Crassostrea virginica, Argopecten irradians, Crepidula fornicata*) across a eutrophication gradient in the Peconic Estuary, NY, USA. Estuaries & Coasts . 36: 1274-1291.

* Rosa, M., **J.E. Ward**, S.E. Shumway, G.H. Wikfors, E. Pales Espinosa & B. Allam, 2013. Effects of particle surface properties on feeding selectivity in the eastern oyster *Crassostrea virginica* and the blue mussel *Mytilus edulis*. J. Exp. Mar. Biol. Ecol. 446: 320-327.

Cranford, P.J., **J.E. Ward** & S. Shumway, 2011. Bivalve filter feeding: variability and limits of the aquaculture biofilter. In: S.E. Shumway (ed.), Shellfish Aquaculture and the Environment, John Wiley & Sons Publ., 81-124.

* Kach, D. & **J.E. Ward**, 2008. The role of marine aggregates in the ingestion of picoplankton-size particles by suspension-feeding molluscs. Mar. Biol. 153: 797-805.

* - students trained in the Ward lab & funded by external grants

Five Synergistic Activities and Achievements:

- Elected member of the Connecticut Academy of Science and Engineering, 2013 to present
- Elected co-Chair of the 2014 Gordon Research Conference on Oceans and Human Health, 2012-2014
- Awarded Fulbright Foreign Scholarship, CIES, International studies and research: **1**) University of Exeter, Exeter, United Kingdom, 2011; and **2**) University of Panama, Republic of Panama, 2004
- Director / Lead PI, Interdisciplinary Research & training Initiative on Coastal ecosystems & Human Health (I-RICH), Graduate Training Consortium, NOAA, Oceans and Human Health Initiative, 2008-2013 (completed)
- Awarded NSF, Faculty Early Career Development Grant (CAREER), 1999-2004

Recent Collaborators:

Bassem Allam, Stony Brook Univ.; Ivar Babb, NURTEC, Univ. of Connecticut; Monica Bricelj, Rutgers Univ.; Celia Chen, Dartmouth Coll.; Peter Cranford, Fisheries and Oceans Canada; Hans Dam, Univ. of Connecticut; Lewis Deaton, Univ. of Louisiana; Sylvain DeGuise, Univ. of Connecticut; Fred Dobbs, Old Dominion Univ.; John Drake, Univ. of Georgia; Emanuelle Pales Espinosa, Stony Brook Univ.; Salvatore Frasca, Univ. of Connecticut; Holly Gaff, Old Dominion Univ.; Tamara Galloway, Univ. of Exeter, UK; Randall Hicks, Univ. of Minnesota Duluth; Brian Huey, Univ. of Connecticut; Brian Jackson, Dartmouth Coll.; Milton Levin, Univ. of Connecticut; Bruce MacDonald, Univ. of New Brunswick, St. John, NB, Canada; Robert Mason, Univ. of Conn.; Dianna Padilla, Stony Brook Univ., Stony Brook, NY; Tracy Romano, Mystic Aquarium & Institute for Exploration; Sandra Shumway, Univ. of Connecticut; Charles Wall, Stony Brook Univ.; Gary Wikfors, National Marine Fisheries Service, Milford, CT

Graduate/Post-graduate Advisors:

Melbourne Carriker, Deceased, University of Delaware (MS advisor) Nancy Targett, University of Delaware (PhD advisor)
Bruce MacDonald, University of New Brunswick, Saint John, Canada (Post-doc advisor) Ray Thompson, Memorial University, St John's, Canada (Post-doc advisor)

Advisees in Last Five Years: (total graduate students = 11, total post-docs = 2) <u>Students</u>
Dustin Kach (MS - graduated), University of Connecticut, Groton, CT Maille Lyons (PhD - graduated), University of Connecticut, Groton, CT Dana Frank (MS, PhD - graduated), University of Connecticut, Groton, CT John Doyle (PhD - graduated), University of Connecticut, Groton, CT Maria Rosa (MS - graduated, PhD), University of Connecticut, Groton, CT Melissa Pierce (PhD), University of Connecticut, Groton, CT
Vena Haynes (PhD), University of Connecticut, Groton, CT <u>Post-docs</u>
Maille Lyons (completed), University of Connecticut, Groton, CT & ODU, Norfolk, VA

BUREAU OF AQUACULTURE 190 ROGERS AVE. MILFORD, CT 06460
EMAIL: KRISTIN.DBANICK@SNET.NET
OFFICE: 203-874-0696 EXT 112
CELL: 203-231-8662

Environmental Analyst with over ten years of experience in environmental program implementation, shellfish resource management, environmental health and food protection, and geographic information systems

CONNECTICUT COLLEGE, 09/1989 through 05/1991
Major: Liberal Arts, 60 credits completed

Education:
SOUTHERN CONNECTICUT STATE UNIVERSITY, May 2003, B.S. in Biology
Major: B.S. in Biology, Concentration in Marine Biology
Honors: Graduated *magna cum laude;* Dean's List, Alumni Association Scholarship
UNIVERSITY OF NEW HAVEN, 11/2004 through 5/2006
M.S. in Environmental Health and Environmental Ecology, 19 credit hours completed

Professional Experience: CONNECTICUT DEPARTMENT OF AGRICULTURE, BUREAU OF AQUACULTURE
Environmental Analyst III June 2013 - present
Shellfish Sanitation Program: Acting lead analyst for illness investigations and shellfish recalls; Lead analyst for Connecticut's *Vibrio parahaemolyticus* Control Plan and statewide Vibrio monitoring program; Investigate and make recommendations during illness outbreaks and recalls in order to protect public health and minimize additional illnesses; Design environmental quality studies or comprehensive shoreline assessments; research and evaluate aquaculture programs for hazards and define new policy; serve as department representative on state, regional and national advisory boards, in legislative hearings, on state councils and Interstate Shellfish Sanitation Conference (ISSC) committees; Design environmental quality studies or comprehensive shoreline assessments which involve conducting a site investigation of each property on the shoreline of the town being studied, conducting and evaluating hydrographic studies, pollution source sampling, assessing water pollution control authority (WPCA) treatment quality, and growing area water quality monitoring; Develop GIS data, provide technical assistance, technical analysis and program data to bureau staff and Director, local and state agencies, state legislature, and federal programs; Write and review legislation and assess and formulate policy for existing and emerging industries;

Environmental Analyst II December 2006 – June 2013
Design and conduct shoreline survey pollution source assessments as required by National Shellfish Sanitation Program (NSSP); develop new programs and regulations to implement environmental policy regarding shellfish and aquaculture; prepare informational materials regarding shellfish program policy for state and federal agencies and stakeholders; develop GIS data and provide technical analysis to staff, state and federal agencies; lead analyst for illness investigations; research and evaluate aquaculture programs for hazards and define new policy; serve as department representative on advisory boards, legislative hearings, state councils, environmental committees, etc.

Environmental Analyst April 2004 - December 2006
Conduct site investigation of shoreline properties which included conducting and evaluating hydrographic studies, pollution source sampling, assessing Water Pollution Control Authority (WPCA) treatment quality, and growing area water quality monitoring; analyze sanitary survey and water quality monitoring data to classify growing areas according to federal standards; statistical analysis of data and preparation of comprehensive assessments for each growing area; evaluate applications for shellfishing activities and inspection of shellfish operations for compliance with NSSP guidelines for sanitation, records and HACCP.

YALE UNIVERSITY, MOLECULAR BIOPHYSICS AND BIOCHEMISTRY
Research Assistant August 2003 – April 2004-
Utilize molecular and biochemical techniques in support of RNA structural research in academic setting; responsible for radiation and chemical safety inspections of laboratory.

CONNECTICUT AGRICULTURAL EXPERIMENT STATION, WEST NILE VIRUS SURVEILLANCE PROGRAM
Research Assistant May 2003 – August 2003
Enumerate and identify mosquitoes to species level for virus surveillance and public health protection; establish and maintain colonies; set traps and collect mosquitoes in field.

CONNECTICUT DEPARTMENT OF ENVIRONMENTAL PROTECTION, BUREAU OF WATER MANAGEMENT
Research Assistant May 2002 – November 2002
Collect water, sediment, benthic invertebrate, and plankton samples from Long Island Sound and tributaries; prepare and analyze samples and deliver to laboratory; prepare charts and graphs for analysis of environmental data

Recent Publications and Presentations
February 2014: Northeast Shellfish Sanitation Association Presentation Overview of Connecticut's 2013 *Vibrio parahaemolyticus* Season

February 2014: Milford Aquaculture Seminar/NESSA Joint Session on Vibrio Presentation Regional Overview of the 2013 *Vibrio Parahaemolyticus* Season
Panel Discussion Member

February 2014: Connecticut Shellfish Initiative Presentation
Clean Waters, Safe Shellfish, Christopher Sullivan and Kristin DeRosia-Banick

Spring/Summer 2014: Wracklines Volume 14, Number 1.
Clean Waters, Safe Shellfish, Christopher Sullivan and Kristin DeRosia-Banick December 2013: Industry

Meeting: 2014 *Vibrio parahaemolyticus* Control Plan for CT

January 2013: Connecticut Sea Grant, Municipal Shellfish Gathering
Vibrio Bacteria Guidance for Recreational Shellfishing Programs Presentation

December 2012: Seaweed Regulatory Workgroup Presentation
Seaweed Cultivation in Long Island Sound: An Analysis of Species and Process Specific Hazards

September 2012: 50th Annual Yankee Conference on Environmental Health Presentation Conducting *Vibrio* Illness Investigations

DeRosia-Banick, K. 2012. Naturally-occurring bacteria threat in the Sound. Long Island Sound Study Sound Update Fall 2012.

DeRosia-Banick, K. 2012. State Responds to the Threat of Naturally Occurring Bacteria in Long Island Sound. The Dredge Volume 5(1): Fall 2012.

March 2012: Connecticut Department of Agriculture Bureau of Aquaculture Shellstock Shipper Owner/Operator Training Seminar
Presentation on Changes to Federal Regulatory Guidance for Shellfish Handling

Certificates/Training:
NOAA Remote Sensing for Spatial Analysts 07/18/2008 Introduction to ArcGIS II 03/28/2008
Shellfish Growing Areas (FD242) 05/10/2007
State of CT Department of Public Health Phase I Subsurface Sewage Disposal 03/2006 State of CT Department of Public Health Food Inspector Certification 02/2006
State of CT Department of Public Health Procedures to Investigate Food borne Illness 2005 Seafood HACCP Regulator Training Program (FD249) 05/04/2005
Basic Shellfish Plant Sanitation (FD 140) 01/13/2005
FDA Training Curriculum for State, Local, and Tribal Regulators ***(****Shellfish Curriculum)* 2004-2005
Interstate Shellfish Sanitation Conference Certificate of Hazard Analysis and Critical Control Point (HACCP) Course Completion 10/21/2004
AFDO Seafood Education Alliance Seafood HACCP Training Course 10/12/2004

Committees and Advisory Boards:
Interstate Shellfish Sanitation Conference, Vibrio Research Committee Interstate Shellfish Sanitation Conference, Recall Guidance Committee Connecticut Sea Grant Extension Advisory Board
Connecticut Geospatial Information Council ConnecticutCoastal Health Officials
Sasco Brook Pollution Abatement Committee

Department Of Agriculture, Bureau Of Aquaculture
P.O.Box 97 Milford, Connecticut 06460
Phone (203) 874-0696 ext.125
joseph.decrescenzo@ct.gov

Joseph August DeCrescenzo

To learn and grow as a Microbiologist in the shellfish and Dairy community.

2002-Present State of Connecticut Milford, Connecticut

Microbiologist 2

- Perform Bacteriological analyses of seawater, sewage effluent, and shellfish, Prepare media reagents for bacteriological examination, Maintain records, Perform qPCR for total and pathogenic *Vibrio parahaemolyticus* in oyster meats, Perform histopathological examination on shellfish, Prepare reports, Laboratory Evaluation Officer for both Dairy and Shellfish labs in Connecticut, Evaluate 12 dairy Laboratories and 2 Shellfish Laboratories in Connecticut, Supervise a Microbiologist 1.

1999-2001 State of Connecticut Milford, Connecticu

Microbiologist 1

- Perform Bacteriological analyses of seawater, sewage effluent, and seafood, Process shellfish for histopathological examination, Perform histopathological examination, Prepare media reagents for bacteriological examination, Use a bioassay for the detection of Paralytic Shellfish Poisoning, Maintain equipment and laboratory.

1998 State of Connecticut Milford, Connecticut

Internship

Performed independent research project utilizing histopathogical techniques. Upon completion of project, reported and published data gathered at annual conference.

Publications:

THE PRESENCE OF VIBRIO PARAMAEMOLYTICUS IN CRASSOSTREA AT SPECIFIC LOCATIONS ALONG THE CONNECTICUT AND LONG ISLAND SHORE – FDA SURVEY FOR JUNE 1999 TO JUNE 2000. Leonora Porter and Eugene Zamojcin, State of New York, Department of Enviromental Conservation, 205 North Belle Mead Rd., East Setaucket, NY 11733; Joseph DeCrescenzo, Inke Sunila, and John Karolus, State of Connecticut, Department of Agriculture, Bureau of Aquaculture, P.O. Box 97, Milford, CT 06460

PRINCIPAL DISEASE OF CONNECTICUT'S OYSTERS. Inke Sunila, Josep DeCrescenzo, John Karolus, and John Volk. State of Connecticut, Department of Agriculture, Bureau of Aquaculture, P.O. Box 97, Milford, Connecticut 06460

* HISTOPATHOGICAL SURVEY OF THE QUAHOG, *MERCENARIA MERCENARIA*, ALONG THE CONNECTICUT COASTLINE. Joseph DeCrescenzo, Inke Sunila, John Karolus, and John Volk. State of Connecticut, Department of Agriculture, Bureau of Aquaculture, P.O. Box 97, Milford, Connecticut 06460

References: References given upon request

Education:

1994-1999 Unity College, Unity, Maine
Bachelor Degree in Science, Emphasis in Biology

2004-2006 Southern Connecticut University, New Haven, CT
9 credits in Graduate level Microbiology Courses

University of Delaware, College of Marine Studies
Fall 1998 to Spring 2003

- Ph.D. 2003, Physical Ocean Science & Engineering (GPA: 4.00)
- Advisor: Dr. Richard Garvine, Harrington Professor of Marine Studies

Yale University
Fall 1992 to Spring 1996
B.S. 1996, *cum laude* (GPA: 3.72)

- Majors: Geology and Geophysics (Atmosphere and Ocean Track), Environmental Studies

EMPLOYMENT

Summer 2005 to Present
University of Connecticut, Department of Marine Sciences

- Associate Professor (promoted in 2012)

Yale University, Geology and Geophysics, Department

Fall 2012

- Visiting Fellow (while on sabbatical from University of Connecticut)

Oregon State University, College of Oceanic and Atmospheric Sciences

Fall 2003 to Summer 2005

- Postdoctoral research associate for Dr. J. S. Allen

University of Delaware, College of Marine Studies

Summer 2003 to Fall 2003

- Postdoctoral researcher for Dr. Richard Garvine

University of Delaware, College of Marine Studies

Fall 1998 to Spring 2003

- Research Assistant and Graduate Fellow

Ocean Surveys, Inc., Old Saybrook, CT
Summer 1996 to Fall 1998

- Project scientist in the oceanography department

CURRENT FUNDING

- M. M. Whitney, CAREER: The Influence of Distributed River Inputs and Coastal Embayments on Dynamics of Large Estuaries, National Science Foundation, 6/1/2010-5/31/2015.
- M. M. Whitney (Uconn PI), D. Codiga (URI PI), D. Ullman (URI Co-PI), Collaborative Research: Investigating Tidal Influences on Subtidal Estuary-Coast Exchange Using Observations and Numerical Simulations, National Science Foundation, 9/1/2008-8/31/2013.
- M. M. Whitney (Uconn PI), F. Bryan (NCAR PI), J. Dennis (NCAR Co-PI), P. MacCready (UW PI), Collaborative Project: Improving the representation of coastal and estuarine processes in earth

system models, Department of Energy, 9/1/2011-8/31/2014.

- M. M. Whitney and J. Edson, Sea Breezes and Estuary-Shelf Response in Areas with Spatial Sea Surface Temperature Variability and Complex Coastal Geometry, National Aeronautics and Space Administration, 1/1/2013-12/31/2015.
- M. M. Whitney and P. Vlahos, Measuring and Predicting the Fate and Transport of Perfluorinated Contaminants Entering the Long Island Sound from Municipal Wastewater in the Housatonic Watershed, Connecticut Sea Grant, 2/1/2012-1/31/2015.

TEACHING AND ADVISING

- MARN 170 & MARN 171 (now MARN 1002 & 1003) Introduction to Oceanography (Fall 2005-2010)
- MARN 172 (now MARN 1004) Introduction to Oceanography Laboratory (Fall 2005-2010)
- MARN 270 (now MARN 4060) Descriptive Physical Oceanography (Spring 2007-2011, Fall 2012-2014)
- MARN 410 Coastal Ocean Circulation (Spring 2006, Fall 2007)
- MARN 5898 Special Topics: River Influences in the Marine Environment (Spring 2012-2013)
- Major advisor for 3 PhD students and 2 Masters students
- Associate advisor for 3 PhD students and 4 Masters students
- Undergraduate advisor for Marine Sciences and Environmental Sciences students

PEER-REVIEWED PUBLICATIONS

- **Whitney, M. M**., D. L. Codiga, D. S. Ullman, P. M. McManus and R. Jiorle. Tidal Cycles in Stratification and Shear and Their Relationship to Gradient Richardson Number and Eddy Viscosity Variations in Estuaries. *J. Phys. Oceanogr.*, 42, 1124-1133.
- O'Donnell, J., R. Wilson, K. Lwiza, **M. M. Whitney**, W. F. Bohlen, D. L. Codiga, T. Fake, M. Bowman, J. Varekamp. 2013. *Physical oceanography of Long Island Sound*. Elsevier, in press.
- **Whitney, M. M**. and D. L. Codiga. 2011. Response of a large stratified estuary to wind events: Observations, theory, and simulations of Long Island Sound. *J. Phys. Oceanogr.*, 41, 1308-1327.
- Xia, M., L. Xie, L. J. Pietrafesa, and **M. M. Whitney**. 2011. The response of a Gulf estuary plume to wind forcing: its connection with salt flux and a Lagrangian view. *J. Geophys. Res.*, doi: 10.1029/2010JC006689.
- **Whitney, M. M**. 2010. A study on the variability of river discharge and salinity in the Middle Atlantic Bight and Long Island Sound. *Cont. Shelf Res.*, 30, 305-318.
- **Whitney, M. M.** and J. S. Allen. 2009. Coastal wind-driven circulation in the vicinity of a bank: Part 1. Modeling flow over idealized banks. *J. Phys. Oceanogr.*, 1273-1297.
- **Whitney, M. M.** and J. S. Allen. 2009. Coastal wind-driven circulation in the vicinity of a bank: Part 2. Modeling flow over the Heceta Bank complex. *J. Phys. Oceanogr.*, 1298-1316.
- Rice, A. E., **M. M. Whitney**, R. W. Garvine, and P. Huq. 2008. Energetics in Delaware Bay: Comparison of two box models with observations. *J. Mar. Res.*, 66, 873-898.
- **Whitney, M. M**. and R. W. Garvine. 2008. Estimating tidal current amplitudes outside estuaries and characterizing the zone of estuarine tidal influence. *Cont. Shelf Res.*, 28, 280-290.
- Garvine, R. W. and **M. M. Whitney**. 2006. An estuarine box model of freshwater delivery to the coastal ocean for use in climate models. *J. Mar. Res*., 64, 173-194.
- Wetz, M. S., B. Hales, P. A. Wheeler, Z. Chase, and **M. M. Whitney**. 2006. Riverine input of macronutrients, iron, and organic matter to the coastal ocean off Oregon, USA, during the winter. *Limnol. Oceanogr.*, 51, 2221-2231.
- **Whitney, M. M.** and R. W. Garvine. 2006. Simulating the Delaware buoyant outflow: Comparisons to observations. *J. Phys. Oceanogr.*, 36, 3-21.
- Tilburg, T. E., J. T. Reager, and **M. M. Whitney**. 2005. The physics of blue crab larval recruitment in Delaware Bay: A model study. *J. Mar. Res.*, 63, 471-495.
- **Whitney, M. M.** and R. W. Garvine. 2005. Wind influence on a coastal buoyant outflow. *J. Geophys. Res.*, 110, doi:10.1029/2003jc002261.
- **Whitney, M. M.** 2003. Simulating the Delaware Coastal Current. University of Delaware dissertation.

SCIENTIFIC OUTREACH AND PROFESSIONAL SERVICE

- Presenter for over 40 scientific oral and poster presentations at colleges and regional and international conferences
- Contributor to many science outreach workshops including the Groton Maritime Academy, Northeast Academy Math and Science Day, and "Y.E.S. I Can" (Youth Endeavoring to Succeed)
- Convener of 2012 Middle Atlantic Bight Physical Oceanography and Meteorology Workshop
- Co-convener of special sessions at 2010, 2012, 2014 AGU Ocean Sciences Meetings
- Reviewer for the National Science Foundation, Sea Grant, Journal of Physical Oceanography, Journal of Marine Research, Journal of Marine Systems, and Estuaries and Coasts
- Member of American Geophysical Union, Coastal and Estuarine Research Federation, and Thames River Basin Commission

AWARDS

- National Science Foundation CAREER Award (2010)
- College of Marine Studies Frances Severence Award for best thesis in Physical Ocean Science & Engineering (2004)
- College of Marine Studies E. Sam Fitz Award for academic excellence (2003)
- University of Delaware Competitive Fellowship (2000, 2001, 2002)
- American Meteorological Society/NOAA Scholarship (1998)
- Yale University Pat Wilde Prize for excellence in marine geology and oceanography (1996)
- American Meteorological Society Howard H. Hanks Scholarship (1995)

CONTRACT

Between

Interstate Shellfish Sanitation Conference
and
Pacific Shellfish Institute

This Contract shall be effective from October 1, 2014 to August 31, 2015, between the Interstate Shellfish Sanitation Conference, (hereinafter referred to as ISSC) and the Pacific Shellfish Institute (hereinafter referred to as the Contractor).

The parties to this Contract agree as follows:

I. SCOPE OF WORK

Identify and evaluate the effectiveness of techniques and practices that could potentially reduce the risk of Vibrio illnesses. The study will offer viable control options for the shellfish industry that will reduce risk of Vibrio illnesses. The study will consider issues associated with the effects of water temperature on initial levels at harvest and the effects of post-harvest temperature control as a means of reducing risk of illness. The detail of this work is in the Proposal which is a part of this Contract.

II. TIME OF PERFORMANCE

This Contract shall be effective from October 1, 2014 and reported on by August 31, 2015. A final report shall be submitted within thirty (30) days of the end of the contract period.

III. COMPENSATION

The total amount of the contract shall be Twenty Nine Thousand One Hundred Eleven and no/100 ($29,111.00) dollars.

IV. METHOD OF PAYMENT

The initial payment shall be for one-half of the contractual amount. The balance is payable upon completion of the contract and the submission of an acceptable final report.

V. TERMS AND CONDITIONS

A. The Contractor shall agree to make positive efforts to utilize the services and products of small and minority owned businesses and individuals where applicable.

B. Any changes to this Contract, which are mutually agreed upon between ISSC and the Contractor shall be incorporated in written amendments to this Contract.

C. The Contractor shall maintain and retain all records and other documents relating to this Contract for a period of twenty-four (24 months from the date of final payment under the Contract, and shall make the documents available for inspection and audit by authorized ISSC and Federal officials.

D. No person shall be excluded from participation, be denied the benefits of, or be subjected to discrimination in relation to any activities carried out under this Contract on the grounds of race, color, sex, religion or national origin.

E. All project deliverables included on Page 9 of 26 of the Pacific Shellfish Institute Proposal (attached) shall be completed. In the event all deliverables are not fully rendered as provided for in the Contract, any monies which have been paid by the agency under the Contract must be refunded to ISSC.

F. The contractor will submit a progress report no later than June 15, 2015. This progress report shall be a summary of activities completed (a brief summary of no more than two (2) pages).

G. Notwithstanding any other provisions of the Contract, the parties hereto agree that the charges to ISSC by the Contractor are payable from federal grant monies. In the event sufficient grant monies are not made available to ISSC to pay the charges hereunder, this contract shall terminate without further obligation of ISSC. In such event, the ISSC shall certify to the Contractor the fact that sufficient funds are not available to ISSC to meet the obligations of the Contract and such written certification shall be conclusive upon the parties.

H. The Contractor certifies that he/she shall not engage in the unlawful manufacture, distribution, dispensation, possession or use of a controlled substance in the performance of this Contract. This certification also applies to any individual employed by the Contractor.

I. The performance of work under this contract may be terminated by the Executive Director, ISSC, in accordance with this clause whenever he shall determine that such termination is in the best interest of the ISSC. The ISSC shall pay all reasonable costs associated with this Contract that the Contractor has incurred up to the date of termination of the contract. Two (2) weeks advance notice of the Contract termination will be provided by the Executive Director, ISSC. Either party may terminate this Contract by giving written notice at least 14 days prior to the effective date of such termination.

J. All records, documents, and reports developed in the performance of this contract shall be the property of and available to the ISSC for its use without payment of royalty or additional cost and shall not be subject of an application for a copyright by, or on behalf of, the contracted Contractor.

VI. The Contractor shall deliver to the ISSC, on or before the final date of this Contract, one electronic copy (Microsoft Word) and three hard copies of the final report.

The parties to this Contract hereby agree to any and all provisions as stipulated above.

AS TO ISSC	AS TO THE CONTRACTOR
BY: _____	BY: _____
TITLE: _____	TITLE: _____
DATE: _____	DATE: _____
WITNESSES:	WITNESSES:
_____	_____
_____	_____
MAILING ADDRESS:	MAILING ADDRESS:
209-2 Dawson Road Columbia, SC 29223-1740	_____ _____
EMPLOYER ID#:	EMPLOYER ID#:
52-1656630	_____

Pacific Shellfish Institute Proposal
Techniques and Practices for Vibrio Reduction

1. Executive Summary

Vibrio parahaemolyticus is a common bacterial contaminant of bivalve shellfish, primarily oysters, and a major source of seafood-related food poisoning. Numerous outbreaks of *V. parahaemolyticus* illnesses associated with consumption of raw or poorly cooked shellfish have occurred between 1997 and 2013, both in the United States and elsewhere. On the U.S. West Coast and particularly in Washington, elevated *V. parahaemolyticus* levels in waters where shellfish are grown, and associated illnesses, continue to cause extensive seasonal harvest closures and product recalls. The closures cause reduced farm and harvester revenue, payrolls, and lost opportunity for tribal and recreational harvest. *V. parahaemolyticus* levels in many growing areas nationwide appear to be increasing and outbreaks could occur with higher frequency and severity across a greater geographic range in the future.

The Pacific Shellfish Institute (PSI) has been engaged in laboratory and field experiments focused on *Vibrio* for over a decade. We believe existing research provides preliminary evidence that elevated *V. parahaemolyticus* levels in intertidal cultivated shellfish can be mitigated by on-site exposure to ambient water conditions. In Washington State and other locations with access to tidelands, shellfish farmers have an enhanced ability to apply innovative post-harvest methods for reducing *V. parahaemolyticus* in their oysters and other shellfish crops, but further studies are needed. In all likelihood, findings would be relevant to other *Vibrio* strains and certainly to other coastal regions. We propose the following two low- cost, high-return ideas for ISSC funding:

1. **Assess the effectiveness of deepwater to purge *V. parahaemolyticus*.** In preliminary experiments, Taylor Shellfish researcher Kurt Johnson demonstrated the effectiveness of deepwater to purge *V. parahaemolyticus* from oysters collected at beaches with historically high levels. The intake is located at their hatchery in Dabob Bay and can be run 24 hours/day. The temperature in waters from this intake is typically 10.5˚C (51˚F). Oysters placed in this water from warmer intertidal beaches (18˚C, 64˚F average) continued to feed and thus purged bacteria. Levels of MPN/g dropped from >11,000 at day 0 (2 replicates of 3 oysters each, not placed in deepwater) to 2400 or 230 at day 1 (per each 51replicate) and 0 and day 2 (both replicates). Results were less spectacular in oysters from beaches were summertime temperatures reached 40˚C (104˚F) likely due to shock which temporarily halted or greatly slowed feeding and purging behaviors.
2. **Assess the effectiveness of re-immersion in sink floats to purge *V. parahaemolyticus*.** Immersion of oysters in deeper, cooler waters has been used to successfully prevent *V. parahaemolyticus* related illness from oysters in Alaska. Washington Department of Health (WDOH) is currently testing its potential in collaboration with a local South Puget Sound producer. These proposed experiments will collaborate with that same producer, and with another producer, also located in a growing area with historically high levels of *V. parahaemolyticus.*

The current management of *V. parahaemolyticus* in shellfish focuses on two primary tactics: (1) closure of growing areas for harvest when contaminated shellfish are found and when environmental factors indicate high risk of further contamination, and 2) restriction of post-harvest times to refrigeration. Most other measures tend to alter the freshness of the product, have uncertain efficacy, and increase the cost to the processor and consumer. PSI and others have investigated a few alternative tactics that showed promise but were inconclusive due to low levels of naturally occurring *V. parahaemolyticus* which limited experimental treatment, and problems with the analytical technique used to quantify *V. parahaemolyticus*. The relay of oysters to waters with lower ambient *V. parahaemolyticus* levels and/or different temperature and salinity conditions was particularly encouraging. The focus of the proposals outlined here, to ISSC, center on the relay of oysters from intertidal culture to: 1) recirculating tanks with deepwater; and (2) sink floats with deeper water.

PSI staff is familiar with the particular challenge of studying *Vibrio* in the field (e.g., identification of appropriate study sites, specialized sample collection and transport needs to avoid cross contamination, etc.). Furthermore, we have a long-standing relationship with the West Coast shellfish aquaculture industry, including Pacific Coast Shellfish Growers Association (PCSGA) members and staff. Recent and proposed PSI research features strong collaboration with both shellfish farmers and regulatory agencies, including the WDOH and FDA. If selected through this 2014 ISSC RFP, PSI would collaborate closely with these entities to complete the proposed research.

2. Approach and Methodology

The proposed research is a collaborative effort to address the project objectives in one year. The research has two primary integrated task elements which assess the potential of alternative post-harvest tactics to suppress the development of *V. parahaemolyticus* in oysters. Ancillary assessments will address some current practices associated with the monitoring of *V. parahaemolyticus* in oysters.

All experiments will depend upon the presence of naturally occurring *V. parahaemolyticus*, so field trials will target sample sites identified as having elevated *V. parahaemolyticus* levels during routine WDOH monitoring. These will likely be the same as those used in previous studies, which consistently exhibit high levels of *V. parahaemolyticus* during the summer months (Figure 1).

All samples will comprise 13 representative oysters taken from the same tidal elevation and the same general area at each study area. Nine oysters will be assayed for *V. parahaemolyticus*, 3 will be reserved for measurement of internal temperatures, accidental loss, and laboratory error, and 1 oyster will be delivered to WDOH for validation of assay results by their laboratory. Oysters will be in the shell with no gapers or broken shells. Oysters will be rinsed with fresh or sea-water to remove sediment, and then be placed in waterproof plastic bags and held on ice or in refrigeration prior to shipment for assay. Holding and shipping conditions and procedures will be the same as those used by WDOH,

except in the ancillary studies which directly assess those procedures.

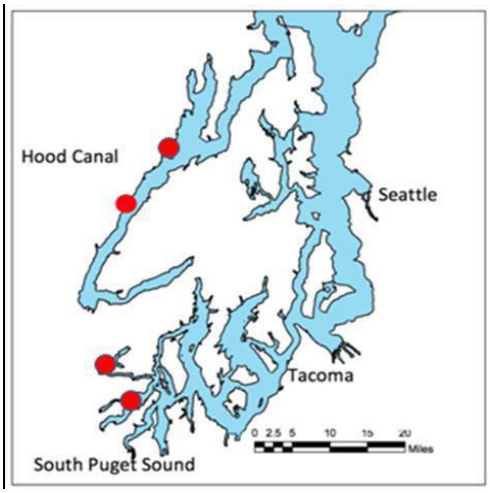


Figure 1 Likely locations of study sites.

Samples will be analyzed by the Environmental Engineering Laboratory (EEL), part of the Institute of Environmental Health (IEH), (IEHEEL) in San Diego, and by WDOH for quantitative PCR to gather MPN/g of *V. parahaemolyticus*. The laboratories feature high throughput realtime PCR protocol to quantify *V. parahaemolyticus* (*V.p.*), thermolabile hemolysin (tlh+), and thermostable-direct hemolysin positive (tdh+) *V.p.* This assay provides quantitative results for both *V.p.* and tdh+ *V.p.* in as little as 24 hours. The protocol will be similar to the multiplexed real- time PCR TaqMan fluorescent probe assay described in Ward and Bej (2006). Shipping methods will be the same as the WDOH methods using Styrofoam shipping boxes and gel packs for refrigeration, except when those methods are compared with alternative tactics.

Transfer Permits will be acquired from the Washington Department of Fish and Wildlife in association with the transport of oysters among areas.

Task 1. **Compare levels of *V. parahaemolyticus* clearance in oysters from areas with consistently high levels of *V. parahaemolyticus* after holding in deepwater intake for various time intervals.**

We propose to augment Kurt Johnson's preliminary studies in collaboration with Mr. Johnson and Taylor Shellfish. Three separate studies will be conducted in succession:

- Purging will be reduced from 24, 48, and 72 hrs to 12, 24, and 36 hrs (untreated oysters from time 0 will also be assayed for levels of *V. parahaemolyticus*).
- Temperature of the deepwater will be elevated by 5˚C to test purging in oysters from especially warm beaches.
- A third test will be conducted to further refine or more precisely test the result of either of the first two tests.

For each experiment, oysters removed from the deepwater treatment will be immediately placed in ice-slurry for ½ hr prior to packing with gel ice pack and shipped with over-night delivery to the laboratory for analysis, in keeping with Mr. Johnson's previous protocols.

The internal temperatures of an ancillary replicate sample of oysters will be measured prior to ice-slurry and shipment.

Task 2. **Compare levels of *V. parahaemolyticus* clearance in oysters from areas with consistently high levels of *V. parahaemolyticus* to oysters resubmerged in nearby deeper cooler waters using sink floats.**

This technique has been used to successfully prevent *V. parahaemolyticus* illness from oysters in Alaska and WDOH is currently testing its potential in collaboration with a local South Puget Sound producer. These proposed experiments will collaborate with that same producer, and with another producer, also located in a growing area with historically high levels of *V. parahaemolyticus*.

The experiment will be conducted at each study site, beginning when numbers of total *Vibrio* and *tlh+* numbers are elevated, as determined in consultation with WDOH. For each experiment, 3 replicate samples of oysters will be collected at the experiment's onset and shipped immediately to the laboratory for quantitative assay of *V. parahaemolyticus*. The internal temperatures of 3 ancillary replicate samples will also be measured and tissue will be sampled at the experiment's onset. An additional 12 replicate samples will be placed in a sink float located in deeper, cooler water. Three samples will be removed and shipped for assay at 1, 3, and 7 days post the initial submergence. The internal temperatures will be measured and tissue will be sampled for each of the 3 remaining replicate samples at each sample interval.

Additional observations will comprise:

- During immersion sampling, water temperature will be recorded with temperature loggers. Salinity and dissolved oxygen will also be measured on site to duplicate WDOH protocols. In-water elements will also be measured off-site to provide ancillary information.
- Internal oyster temperatures will be taken along with tissue samples by opening a market sized oyster, pushing the thermometer into the meat as far as the dimple (or 1 inch), and measuring the temperature. This oyster will not be a part of the tissue sample.

Results will be compared among immersion interval and repetition using analysis of variance. Trends among the variables will also be examined visually.

Ancillary assessments

Compare levels of *V. parahaemolyticus* in oysters placed in ice-slurry prior to shipment with ice-gel packs to shipment no ice-slurry treatment and shipment with ice-gel packs only.

Additional pre-treatment samples from the sink-float studies will be assayed for levels of *V. parahaemolyticus* after shipment to the laboratory in California using Mr. Johnson's ice-slurry pre-shipment protocol or WDOH protocol featuring ice-gel packs only. In anticipation of high variability among replicates and low difference between shipment methods, 9 replicate samples per method will be assayed rather than 3.

Validation of California EEL laboratory results with results from WDOH laboratory.

As previously noted, an additional sample at each of the sample interval for both tasks 1 and 2 will be shipped or hand-delivered to WDOH for comparative analysis and validation with their laboratory.

If possible, apply field data to assess key environmental parameters for correlations and interactions with *V. parahaemolyticus* growth and clearance to potentially better predict and manage elevated levels in oysters.

In previous studies, samples collected from areas in Hood Canal, Washington consistently had higher levels of *V. parahaemolyticus* in oysters and sediments compared to samples collected from sites in the southern main basin of Puget Sound, Washington. Water salinity and temperatures are often very similar at these two areas, but Hood Canal is known to differ from the rest of Puget Sound in terms of dissolved oxygen levels, types and abundances of phytoplankton, and the dynamics of water circulation. Further investigation of the oceanographic and biological conditions associated with *V. parahaemolyticus* during the summer season would be of great value in developing tools to predict levels of *V. parahaemolyticus* and areas at risk in Hood Canal and elsewhere.

PSI currently has a moderate data base of the key environmental factors and associated levels of *V. parahaemolyticus* in oysters at the same site and time. Though the proposed studies are small in scale and sample size, they are better replicated than previously, and would augment that base.

Data from all PSI and potentially WDOH studies will be analyzed using correlation analysis, trend and analysis, and potentially multivariate analysis.

3. Project Deliverables

Results of the research outlined above would provide shellfish growers and harvesters across the country with two proactive post-harvest management practices to reduce and/or minimize the risk of *V. parahaemolyticus* derived food poisoning in raw and under-cooked shellfish.

Specific deliverables would be recommendations toward the feasibility of submerging oysters with high levels of using *V. parahaemolyticus* in 1) recirculating deepwater and 2) deeper cooler water using sink floats. These tactics would allow oysters to purge and depurate *V. parahaemolyticus.* For each tactic, recommendations will include optimal post-harvest holding temperatures and duration for effective *Vibrio* reduction. In addition to ongoing discussions with research collaborators (Taylor Shellfish and WDOH), recommendations will be detailed in a final report to ISSC. The final report will summarize the scope, approach, results, statistical analysis of results, and recommendations stemming from this research.

Adoption of these post-harvest management practices would improve harvest predictability during periods of potential *V. parahaemolyticus* contamination in shellfish, increase consumer confidence in the safety of the products, reduce or minimize the *V. parahaemolyticus* related closures, recalls, and associated economic losses.

The proposal outlined above would also complement other *Vibrio* research on shellfish. It would contribute to the cooperative relationships between local, state and federal regulatory agencies, tribes, academic institutions, shellfish growers and scientific consultants distributed along the entire West Coast. Findings would also assist ISSC and public health regulators in providing valuable feedback to the FDA regarding the *V. parahaemolyticus* risk assessment.

4. Project Management Approach

PSI will collaborate closely with Taylor Shellfish and WDOH to establish the location and specifics of the study design outlined in section 2 "Approach and Methodology" above. However, project oversight will be the responsibility of PSI, including financial management. Roles of specific PSI staff will be as follows:

As Executive Director, Bobbi Hudson will be responsible for the organization and management of this grant within PSI. She will actively supervise all PSI staff and subcontractors supported by this grant and conducting the research. Ms. Hudson will also be actively involved in all aspects of the research and the production of the final report to ISSC. She will also be responsible for submitting all necessary financial data and information to fulfill project deliverables and reporting requirements. Ms. Hudson will be actively involved in outcome dissemination and communication of this project.

Dr. Cheney will responsible for final experimental design, data interpretation and contribute to the final report to ISSC.

Dr. Steven Booth will be responsible for experimental design, product procurement, data acquisition, data evaluation, data interpretation and contribute to the final report to ISSC. He will also be actively involved in analysis and reporting and outcome dissemination.

Andy Suhrbier will be responsible for conducting studies, especially sample procurement and data acquisition. He will be involved with finalizing experimental design and collecting

information and data for all activities for this grant. He will be responsible for data evaluation and interpretation with the consulting help of Drs. Cheney and Booth. He will also be actively involved in collaboration with Taylor Shellfish, other shellfish aquaculture farms, WDOH, and the outcome dissemination and communication of this project.

5. Detailed and Itemized Pricing

The research outlined above is detailed by major task below. Laboratory and shipping costs for individual experiments are separated to allow comparison. *PSI encourages ISSC to consider partial funding of this proposal if 100% funding is not available, and/or a portion of this proposal is not of significant interest to ISSC.*

Task 1.

Deep Water: Testing to see timing of depuration of Hood Canal Oysters in 100ft intake water.

Samples:	36 samples in 3 experiments (deepwater, elevated water, best one) 12 Samples each experiment (3 samples at 0, 12, 24 and Overnight shipping (including boxes and ice):	
Sample Analysis:	$168	40
# samples	36	36
Total:	$6,048	$ 1,440
Experimental Total:		$ 7,488

Ancillary comparison of ice-slurry to normal gel-pack shipping

Sample Analysis:	$168	40
ice-slurry # samples	6	6
gel-pack only # samples	9	9
Total:	$ 2,520	$600
Experiment Total:		$3,120

Task 2.

Sink Float: Testing to see timing of depuration of South Puget Sound Oysters in sink floats.

Samples:	24 samples (12 Samples at each site.) 3 samples at 0, 1, 3 and 7 days. Overnight shipping (including boxes and ice):	
Sample Analysis:	$168	40
# samples	24	24
Total:	$4,032	$960
Experiment		$4,992

Budget for PSI staff time and expenses:

Personnel	**Amt. of effort**			
Executive Director	25%	1.50	months	$2,065
Research Director	25%	1.00	months	$1,997
Senior Scientist	25%	1.50	months	$2,408
Senior Biologist	25%	2.00	months	$2,700
Total Salaries and Wages				$9,169
Direct Staff Benefits (35%)				$3,209
Total Personnel Costs				$12,379

Travel

Domestic Travel		
Auto travel ($0.56/mile)	$952	
Other travel (meals & incidental reimbursement)	$180	Total
Travel	$1,132	

As detailed above, the total budget for Task 1, Task 2 and ancillary studies is $29,111. No overhead or indirect fees are included. Matching funds of at least 1:2 can be documented through in-kind and direct expenses associated with Task 1 and Task 2, but exact amounts will depend on which tasks and/or ancillary studies ISSC encourages. Collaboration with WDOH, Taylor Shellfish and two additional shellfish aquaculture farms will be the source of matching funds. If allowable, PSI can also demonstrate matching funds through circumvented indirect costs (PSI's currently approved indirect rate with the Department of Commerce is 46.22%).

Citations:

Ward, L. N. and A. K. Bej (2006). "Detection of *Vibrio parahaemolyticus* in shellfish by use of multiplexed real-time PCR with TaqMan fluorescent probes." Applied and Environmental Microbiology **72**(3): 2031-2042.

Appendix A: References

PSI has conducted numerous grant-funded *Vibrio* studies for the NOAA Saltonstall-Kennedy grant program and the NOAA/National Sea Grant Aquaculture Research Program. Current grant program administrators are:

Dr. Gene Kim

NOAA National Sea Grant Program Director for Aquaculture
(301) 734-1281

gene.kim@noaa.gov

Penelope D. Dalton, M.S.
Washington Sea Grant Director
(206) 685-9215

pdalton@u.washington.edu

All recent PSI studies focused on *Vibrio parahaemolyticus* have included substantial collaboration with the Washington Department of Health, Office of Shellfish and Water Protection, Division of Environmental Public Health. Numerous staff within the division can speak to PSI's research capabilities and *Vibrio* knowledge, but the main point of contact is:

Jerrod Davis, P.E.

Office of Shellfish and Water Protection Director
Washington State Department of Health

(360) 236-3391

Jerrod.Davis@DOH.WA.GOV

Appendix B: Project Team Staffing

Project staff will include executive director Bobbi Hudson, senior scientists Dr. Daniel Cheney and Dr. Steven Booth, and senior biologist Andrew Suhrbier. All staff is familiar with the particular challenge of studying *Vibrio* in the field, including identification of appropriate study sites, specialized sample collection and transport needs to avoid cross contamination. PSI staff will also work closely with Kurt Johnson at Taylor Shellfish, and Washington Department of Health staff, including Laura Wigand. Recent and currently proposed PSI research features strong collaboration with both shellfish farmers and regulatory agencies, and this project would continue PSI's well-established reputation in this regard.

All PSI project staff is hourly or salaried regular employees of PSI. PSI carries a $2,000,000 business liability insurance policy and a $1,000,000 Directors and Officers (D&O) insurance policy. No current PSI employees have ever been convicted of a felony.

Biographies follow for the following PSI staff that will contribute to this project:

a. Bobbi Hudson, MSc, *Executive Director*
b. Daniel Cheney, PhD, *Research Director*
c. Steven Booth, PhD, *Senior Scientist*
d. Andrew Suhrbier, BSc, *Senior Biologist*

Pacific Shellfish Institute
120 State Ave NE #1056, Olympia, WA 98501
Tel: (360) 754-1359; Cell: (360) 490-6910
Email: bobbi@pacshell.org

PROFESSIONAL QUALIFICATIONS
M.S., Evergreen State College – Environmental Science -- 2005
B.S., Evergreen State College – Environmental Science, Fisheries -- 2001

DISSERTATIONS
MS thesis: *Environmental, economic & policy considerations of the net-pen salmon farming industry in Washington State*

PROFESSIONAL COLLABORATIONS
Thom Allen, Alexis Bond, Steven Booth, Susan Burke, Daniel Cheney, Aimee Christy, Leah Cuyno, Jonathan Davis, Ralph Elston, Joao Ferreira, Caroline Friedman, Julie Hampden, Molly Jackson, Teri King, Brian Kingzett, Leah Kuehl, David Landkamer, Mary Middleton, Danna Moore, Betsy Peabody, David Preikshot, Kristin Rasmussen, William Schenken, Sue Shotwell, peter Steinberg, Andrew Suhrbier, Brent Vadopalas, Katherine Wellman

PROFESSIONAL AFFILIATIONS
Member, National Shellfisheries Association

RELAVENT EXPERIENCE
Executive Director, Pacific Shellfish Institute, Olympia, Washington, July 2013 – Present
The Pacific Shellfish Institute (PSI) is a non-profit research organization originally created by the Pacific coast commercial shellfish industry in 1995. PSI retains a diverse portfolio of biological, oceanographic and social science research projects. Routine tasks of the executive director include grant and technical writing, research design and execution, presentations, public outreach, response to public, government and media inquiries and overall management of the organization. Bobbi's primary research interests include valuation of ecosystem services, economic impacts of shellfish cultivation, social and ecological carrying capacity, and intertidal ecology. Bobbi also specializes in evaluation of sustainable bivalve aquaculture production in near shore environments.

Research Biologist, Pacific Shellfish Institute, Olympia, Washington, Nov. 2006 – June 2013
Conducted research, project management, and technical writing. Contributed to applied research projects on the interactions of shellfish culture with the natural environment, organic pollutants, and disease and environmental stress. Directed a multi-faceted project evaluating the benefits and costs of shellfish in Washington State, and a survey-based study of the economic contributions of the West Coast shellfish industry. Served as an inspector for sustainable shellfish product certifications.

Public Information Officer, Wash. Dept. Retirement Systems, Olympia, WA, Feb. 2002 – Dec. 2005 Produced a wide variety of print and web-based communications for agency staff, retirees, public officials and the Governor. Communications lead to implement new legislation.

Biological Science Technician, U.S. Fish and Wildlife Service, Flagstaff, AZ, Oct. 1998 – Sept. 2000 Conducted fisheries research in remote areas of Grand Canyon National Park and adjacent tribal lands. Prepared reports and delivered presentations about research and analysis at regional meetings. Extensive research, writing and editing of technical reports, some published. Trained other personnel in fish species identification, PIT tagging ESA species, and habitat classification.

SELECTED PUBLICATIONS & REPORTS

Wellman, K.F., **Hudson, B.M**., Schenken, W.S., Bond, A. and L. Cuyno. *In prep*. The Economic Impact of Shellfish Aquaculture in Washington State.

Hudson, B., Christy, A., and A. Suhrbier. 2014. Nutrient bio extraction using wild set of blue mussel (*Mytellis trossulus*) in Budd Inlet, Southern Puget Sound, Washington State. *Abstracts*: 106th Annual Meeting, National Shellfish Association, Jacksonville, FL. (abstract).

Davis, J., Vadopalas, B., Suhrbier, A., Cheney, D., Middleton, M., **Hudson, B**., Rasmussen, K., Kuehl, L. and C. Friedman. 2012. Growth and Maturation in Triploid Pacific Geoducks (*Panopea generosa)* in Puget Sound, Washington. *Abstracts* World Aquaculture Society (WAS)/National Shellfisheries Association (NSA)/American Fisheries Society (AFS) Finfish Section meeting, Nashville, Tennessee, February 21-25, 2013. (abstract).

Hudson, B. and K. Wellman. 2012. Economic impact of West Coast shellfish aquaculture. *Abstracts*: 104th Annual Meeting, National Shellfish Association, Seattle, WA. (abstract).

Davis, J., Vadopalas, B., Jackson, M., Suhrbier, A., Cheney, D., Middleton, M., **Hudson, B**., Rasmussen, K., Kuehl, L. and C. Friedman. 2013. Performance of Triploid Geoducks. *Abstracts*: 104th Annual Meeting, National Shellfish Association, Seattle, WA. (abstract).

Hudson, B. 2011. Washington State Shellfish Production and Restoration - Environmental and Economic Benefits and Costs. National Sea Grant Final Report for NA08OAR4170822.

Gorman, O., R. Bramblett, **B. Hervin (Hudson)**, D. Van Haverbeke, and D. Stone. 2005. Distribution and abundance of native and non-native fishes of the Colorado River ecosystem in Grand Canyon, Arizona, p. 78–94. In: M. Brouder, C. Springer, and S. Leon (eds.). The lower Colorado River: restoring natural function and native fish within a modified riverine environment; proceedings of July 8–9, 1998 and July 13–14, 1999 symposia in Las Vegas. U.S. Fish and Wildlife Service, Albuquerque, NM. 188 p.

SELECTED PRESENTATIONS

What's All the Fuss About? Gauging Public Perceptions of Shellfish Farming. Washington Sea Grant 21st Conference for Shellfish Growers. Union, Washington, March 3-4, 2014.

Engaging and Communicating with the Public: A Review of Creative Seafood and Fisheries-Related Outreach Tools, Technologies and Activities. Pacific Coast Shellfish Growers Association (PCSGA)/National Shellfisheries Association (NSA)-Pacific Coast Section 67th Annual Shellfish Growers Conference. Sunriver, Oregon, October 1-3, 2013.

Economic Impact of West Coast Shellfish Aquaculture. National Working Waterfronts & Waterways Symposium. Tacoma, Washington, March 25-28, 2013.

Money & Jobs: The Economic Impact of Shellfish Aquaculture in WA, OR & CA. Pacific Coast Shellfish Growers Association (PCSGA)/National Shellfisheries Association (NSA)-Pacific Coast Section 66th Annual Shellfish Growers Conference. Tulalip, Washington, September 24-27, 2012.

Environmental, Economic & Social Benefits of Washington State Shellfish Production. World Aquaculture Society (WAS)/National Shellfisheries Association (NSA)/American Fisheries Society (AFS) Finfish Section meeting, San Diego, California, March 1-5, 2010.

Hudson, B., Cheney, D., Wellman, K., Davis, J., Peabody, B., Steinberg, P., Hampden, D., and S. Burke. 2010. Environmental, Economic & Social Benefits of Washington State Shellfish Production. World Aquaculture Society (WAS)/National Shellfisheries Association (NSA)/American Fisheries Society (AFS) Finfish Section meeting, San Diego, California, March 1-5, 2010 (poster).

Biographical Sketch Daniel P. Cheney

Pacific Shellfish Institute
120 State Ave NE #1056, Olympia, WA 98501
Tel: (360) 754-2741; Fax: (360) 754-2246; Cell: (360) 791-2796
Email: cheney@pacshell.org

PROFESSIONAL QUALIFICATIONS

Ph.D., University of Washington -- Fisheries, Physiology --
1975 M.S., University of Hawaii -- Zoology, Biochemistry -
- 1967
B.S., University of Washington -- Fisheries, Mathematics --
1964 Postdoctoral, Vanderbilt University – Zoology – 1973

PROFESSIONAL COLLABORATIONS

Peter Becker, Steve Booth, Aimee Christy, Jeffery Cordell, Jonathon Davis, William Dewey, Brett Dumbauld, Ralph Elston, Dennis Hedgecock, Bobbi Hudson, Joao Ferreira, Carolyn Freidman, Adam James, Kurt Johnson, Gordon King, Chris Langdon, Jeff Layton, David Preikshot, Andrew Suhrbier, Brent Vadopalas

PROFESSIONAL AFFILIATIONS

Member, World Aquaculture Society
Member, past member-at-Large and section Chairman, National Shellfisheries Association

RELAVENT EXPERIENCE

Senior Scientist, 2009 – Present; Executive Director, 1996 – 2009. Pacific Shellfish Institute (PSI). PSI is a non-profit research and public education organization originally created by the Pacific coast commercial shellfish industry. Dan is PSI's project developer, principal investigator and research scientist for regional and federally funded applied research to: 1) examine the environmental and economic interactions of shellfish production practices; 2) develop new species and production methods; 3) explore methods to control *Vibrio* bacteria contamination and reduce the public health risk of raw shellfish; 4) assess pollutants in west coast shellfish and human health risks; 5) examine harvest and production methods to improve shellfish quality; 6) and other related shellfish studies. His associated activities include management of collaborative research teams from regional and national research organizations, presentations of project results at national and international conferences and workshops, and communications with members of the shellfish industry, and the regulatory and research communities. Dan is a board member of the University of Washington Center for Urban Waters, a water quality research and education center based in Tacoma, Washington. He is also a co- owner and board member of Baycenter Farms, an oyster and clam production and processing company based in Willapa Bay, southwest Washington State.

Program Director, 1993 – 1996.

Provided management and technical support for USAID and Asian Development Bank (ADB) funded projects in the south Pacific dealing with development of tuna and bottom fish resources (Tonga and Tuvalu) and a cultured black pearl industry (Cook Islands).

SELECTED PUBLICATIONS

Cheney, D.P. 2010. ***Bivalve shellfish quality: From the hatchery to the consumer***. Journal of the World Aquaculture Society. 41(2):192-206.

Cheney, D.P., Langan, R., Heasman, K., Friedman, B., and Davis, J. 2010. ***Shellfish and shellfish culture in the open ocean: The shellfish farming industry, lessons learned for offshore expansion***. Marine Technology Society Journal. 44(3):55-67.

Cheney, D.P., Davis, J., Ferreira, J., King, T., Preikshot, D., Roberts, and M. Bricker. 2012-2014**.** ***Planning for sustainable shellfish aquaculture in complex multiple use environments: Determining social and ecological carrying capacity for south Puget Sound, Washington*.** NOAA Sea Grant Aquaculture Research Program; progress reports.

Cheney, D.P., Dewey, B., Davis, J., Cordell, and J. Ferreira. 2010-2013. ***Evaluation and development of advanced farm management and harvesting tools for economically efficient and environmentally sustainable production of Manila clams*.** NOAA, Saltonstall-Kennedy Program, Silver Spring, MD; progress reports.

Chae, M. J., D. Cheney, et al. 2009. T***emperature effects on the depuration of Vibrio parahaemolyticus and Vibrio vulnificus from the American Oyster (crassostrea virginica).*** Journal Of Food Science 74(2): M62-M66.

Cheney, D.P. and C. Friedman. 2009-2013. ***Harvest management tools to control the levels of vibrio parahaemolyticus in oysters and other bivalve shellfish*.** NOAA, Saltonstall-Kennedy Program, Silver Spring, MD; progress reports.

Cheney, D.P., Davis, J. and B. Vadopalas. 2009-2013. ***Biosecure domestication of native geoduck clams*.** NOAA, Saltonstall-Kennedy Program, Silver Spring, MD; progress and completion reports.

Burge, C.A., Judah, L.R., Conquest, L.L., Griffin, F.J., Cheney, D.P., Suhrbier, A., Vadopalas, B., Olin, P.G., Renault,
T. and C.S. Friedman. 2007. ***Summer seed mortality of the pacific oyster, Crassostrea gigas Thunberg grown in Tomales Bay, California, USA: the influence of oyster stock, planting time, pathogens, and environmental stressors.*** Journal of Shellfish Research 26(1):163–172.

Cheney, D.P., Davis, J., Luckenback, M., Newell, C., Richardson, J. Getchis, T., Dumbauld, B. and S. Nelson. 2006-
10. ***The environmental effects of alternative shellfish culture methods***. NOAA, National Aquaculture Research Initiative, Silver Spring, MD; progress and completion reports.

Cheney, D.P., Davis, J., Luckenback, M., Newell, C., Richardson, J., Getchis, T. and D. Angel. 2003-05.
Environmental effects of marine shellfish aquaculture on benthic fauna and water column characteristics in the northwest and east coasts of the U.S. NOAA, National Aquaculture Research Initiative, Silver Spring, MD; progress and completion reports.

Cheney, D.P., Macdonald, B.F. and R. A. Elston. 2000. ***Summer mortality of Pacific oysters, Crassostrea gigas (Thunberg): Initial findings on multiple environmental stressors in***

Puget Sound, Washington, 1998. Journal- of-Shellfish-Research 19(1): 353-359.

Cheney, D.P., Suhrbier, A.D., Christy, A.E., Beltran, H.S., Davis, J.P., Brooks, K.M. and F.J. Smith. 2003. ***Mussel growth and food utilization in relation to water column conditions on raft systems in Puget Sound, Washington***. Journal of Shellfish Research 22:324 / NOAA, National Aquaculture Research Initiative, Silver Spring, MD; completion reports.

Cheney, D.P. and T. Mumford. 1986. ***Commercial harvest and culture of shellfish and seaweeds in Puget Sound.***
University of Washington Press, Seattle. 160 p.

Saurel, C., Ferreira, J., Cheney, D., Suhrbier, A., Dewey, B., Davis, Jonathan, and J. Cordell. Submitted. ***Ecosystem goods and services from Manila clam culture in Puget Sound—a modelling analysis***. Aquaculture – Environment Interactions.

Suhrbier, A.D., Cheney, D.P., Middleton, M.E., Booth, S.R., and J.P. Davis. Submitted***.*** ***Examination of farmed geoduck (Panopea generosa gould, 1850) predator protection efficacy and environmental effects***. Journal-of- Shellfish-Research.

Christy, A.E., Cheney, D.P. and I. Stupakoff. 2011. ***Cadmium in Pacific oysters (Crassostrea gigas): A survey of the United States West Coast and Mitigation Strategies.*** World Aquaculture Magazine. 42(1):52-57.

Dewey, W., Davis, J.P. and D.P. Cheney. 2011. ***Shellfish aquaculture and the environment: an industry perspective***, pp. 33-50. In: Shellfish aquaculture and the environment. Shumway, ed. Wiley-Blackwell. 507 p.

Dumbauld, B.R., Booth, S.R, Cheney, D.P., Suhrbier, A and H. Beltran. 2006. ***An integrated pest management program for burrowing shrimp control in oyster aquaculture.*** Aquaculture. 261(3): 976-992.

Elston, R., Cheney, D., MacDonald, B. and A. Suhrbier. 2004. ***Tolerance and response of Manila clams, Venerupis philippinarum (A. Adams and Reeve, 1850) to low salinity***. Journal-of-Shellfish-Research 22(3):667-674.

Hamdoun A.M., Cheney, D.P. and G.N. Cherr. 2003. ***phenotypic plasticity of hsp70 and hsp70 gene expression in the pacific oyster (Crassostrea gigas): Implications for thermal limits and induction of thermal tolerance***. Biol. Bull. 205:160-169.

Elston, R.A. and D.P. Cheney. 2000. ***Shellfish high health program.*** Journal-of-Shellfish-

Research 19(1): 688-689. Herwig, R.P., Estes, R.M., Messey, C.L., and D.P. Cheney. 2000***.***

Distribution of Vibrio parahaemolyticus in Puget Sound oysters, water, and sediments during summer 1999. Journal-of-Shellfish-Research 19(1): 657.

Pacific Shellfish Institute
120 State Ave NE #1056, Olympia, WA 98501
Tel: (360) 754-1359; Cell: (360) 490-6910
Email: bobbi@pacshell.org

PROFESSIONAL QUALIFICATIONS
Ph.D., Oregon State University -– Entomology --
1992 M.S., Western Washington University –-
Biology -- 1982 B.A., University of Iowa –
Zoology -- 1975

PROFESSIONAL COLLABORATIONS
Dr. Kim Patten, Dr. Chris Grue, Dr. Brett Dumbauld, Dr. Joth Davis, Kurt Johnson

PROFESSIONAL AFFILIATIONS
Member, National Shellfisheries Association

RELATED EXPERIENCE
Sr. Scientist, Pacific Shellfish Institute, Olympia, Washington, Fall 2007 – Present Collaborate with other scientists to study issues related to bivalve aquaculture. Developed experimental designs and protocols, executed them, analyzed results, and presented findings both orally and in writing to scientific and grower groups.

IPM Coordinator, Willapa Grays Harbor Oyster Growers Association, Summer 2001- February 2011. Coordinated activities among growers, investigators, and regulators to develop and implement an IPM plan for burrowing shrimp on commercial oyster beds. Primary and ghost author of several grants to fund research projects involving physical, cultural, and biological control alternatives to carbaryl application. Principal investigator of study of the impact of carbayl on the benthic infauna and co-investigator of several other studies of alternative management tactics. Contributed to development of NPDES permit, NWP 48 Biological Assessment: Screening Level Risk Assessment to Threatened and Endangered Species from the Use of Carbaryl to Control Burrowing Shrimp in Washington State Shellfish Aquaculture, and furnished Commentary on Draft Biological Opinions Issued under the Endangered Species Act.

Consultant Entomologist / Research Scientist, Winter 2000 -2007. 1) In collaboration with Frem Biosciences, research and development of organic slug control materials. 2) Occasional consultant for Crop Health Advising & Research, Kelowna, B.C. regarding root weevil management strategies. 3) In 2003, I completed a study to "Define the status of the invasive cranefly, *Tipula oleracea* L., as a pest in Oregon and Washington: its biology, distribution, and management potential" funded by contracts with WSDA and ODA Nurserymen Associations. 4) Authored QAPP for Pacific Conservation District for "Grayland Cranberry Water Quality BMP Project" for submission to Wash. State Dept. of Ecology.

Research Associate & Consultant Spring, 1998-Winter 2000. Washington State University Long Beach Res. Unit & Pacific Coast Cranberry Research Foundation. Evaluated biorational insecticides and improved tactics to better manage insect pests of cranberry. Implemented "low-risk" insect IPM program via on-farm demonstration trials, grower workshops, and extension bulletins. Monitored seasonal and geographic distributions of recently introduced pests.

Research Associate Spring 1993-Spring 1998. Washington State University Vancouver Res. & Ext. Unit. Investigated non-chemical control strategies, especially microbials, to suppress subterranean insect pests of small fruits. Isolated indigenous strains of entomopathogenic fungi, compared their virulence in laboratory bioassays, and, in collaboration with colleagues at Oregon State University,

sequenced their genomes using PCR techniques. Developed a low-cost technology to produce, at moderate scales, a dried mycelium formulation of *Metarhizium anisopliae* and demonstrated its efficacy against black vine weevil and cranberry girdler. Investigated the mechanism of induced resistance to spider mites in raspberry and strawberry.

Postdoctoral Fellow Summer 1991-Spring 1993. Kelowna, B.C. British Columbia Fruit Growers Association. Investigated and implemented predator-compatible program to manage pear pests in the Okanagan Valley. Investigated "soft" insecticides, alternative ground covers or hedgerows, and other tactics to encourage indigenous natural enemy immigration to pear. Compared season-long alternative programs to standard programs among commercial blocks. Several field and laboratory trials focused on the predatory potential of the European earwig, *Forficula auricularia*, and the predaceous mirid, *Deraeocoris brevis*.

Research Cooperator Spring 1991. Oregon State University. Investigated potential of mating disruption/pheromone confusion for orange tortrix in Oregon caneberries. Conducted preliminary survey of predator and phytophagous mites on hops in the Willamette Valley, OR

Graduate Teaching Assistant 1990. Oregon State University, Corvallis, OR. IPM III.

Certification Inspector 1990-1991. Oregon Tilth. Inspected farms for compliance with standards of organic production and made recommendations to certification committee.

Graduate Research Assistant 1986-90. Oregon State University, MCAREC. Hood River, OR. To fulfill Ph.D. requirements, completed course work and conducted dissertation. Described the taxonomic composition of a complex of 43 arthropod natural enemies that colonize and suppress pear psylla in orchards of differing chemical regime, orchard structure, and vegetational setting.
Research Assistant 1983-1987. Oregon State University. Investigated the economic entomology of several orchard pests and beneficials. Conducted pesticide trials, monitored pheromone traps in whole of upper Willamette Valley, determined thresholds of pupal development for apple maggot and walnut husk fly, analyzed data, prepared graphs, and supervised several part-time employees.

Environmental Consultant 1982. Bellingham, WA. Assessed the suitability of ten small streams in the Nooksack Watershed for the establishment of small scale hydro-electric power plants. An index of food available to salmonid populations was calculated based on the abundance and composition of the benthic community at high and low elevations, early and late season, at mid-day and mid-night. Aquatic invertebrates were sampled by surber, kick, and drift-net. Salmonids were sampled by electroshock, and the stomach contents were frequently

examined.

Graduate Teaching Assistant 1980-1982. Western Washington University. General Entomology, Aquatic Entomology, Field Entomology, Alpine Limnology, Biological Kingdoms, Introductory Biology; 1991. Oregon State University. IPM III.

RELEVANT PUBLICATIONS AND REPORTS

Booth, S.R. 2012, revised 2014. Dichotomous Key and Illustrated Guide to the Pests of Bivalve Aquaculture in Washington and Oregon. Funded by Prime Award No. 2007-51120-03885, Subaward No.07-001492-WAS15 from the USDA National Institute for Food and Agriculture.

Booth, S.R. and K. Rasmussen. 2013. Impact of imidacloprid on epi-benthic and benthic invertebrates: 2011 studies to describe the Sediment Impact Zone (SIZ) related to imidacloprid treatments to manage burrowing shrimp. Submitted to WSU, Oct, 2013.

Booth, S.R. and K. Rasmussen. 2013. Impact of imidacloprid on epi-benthic and benthic invertebrates: 2012 studies to describe the Sediment Impact Zone (SIZ) related to imidacloprid treatments to manage burrowing shrimp. Submitted to WSU, May, 2013.

Booth, S.R. and D. Tufts. 2003 – 2010. Willapa Bay-Grays Harbor Oyster Growers Association Annual Operations Plan for Carbaryl-based Management of Burrowing Shrimp. Submitted to

WDOE June 1 of every year.

Booth, S.R. and D. Tufts. 2002 – 2010. Willapa Bay-Grays Harbor Oyster Growers Association Annual Report for Burrowing Shrimp Management. Submitted to WDOE December 1 of every year.

Booth, S.R. 2007. An Updated Plan for Integrated Pest Management of Burrowing Shrimp on Commercial Shellfish Beds Submitted to: Washington Department of Ecology February 1, 2007. 34 pp.

CURRICULUM VITAE **Andrew D. Suhrbier**

120 State Avenue NE #1056
Olympia, WA 98501
Tel: (360)754-2741; FAX: (360)754-2246; Cell: (360)280-1517
E-mail: suhrbier@pacshell.org

PROFESSIONAL QUALIFICATIONS

B.S. Texas Lutheran University, Seguin, Texas --Molecular Biology, 1996

PROFESSIONAL COLLABORATIONS

Alan Barton, Peter Becker, Jeffery Cordell, Jonathon Davis, William Dewey, Beniot Eudeline, Joao Ferreira, Burke Hales, Adam James, Kurt Johnson, Vassili Kalashnikov, Gordon King, Jan Newton, Kim Patton, Brent Vadopalas

PROFESSIONAL AFFILIATIONS

Member, National Shellfisheries Association

RELAVENT EXPERIENCE

Senior Biologist, Pacific Shellfish Institute, Olympia, WA; 2000 to present
Involved in PSI's marine benthic/water quality sampling and analysis, mapping of marine habitats, data analysis, project development and management. Current projects include the potential of polyculture systems; interactions of shellfish culture with the natural environment; the impact of organic pollutants, and bacterial contaminants on bivalve shellfish; efficiencies of production, and disease and environmental stress studies of shellfish. Interacts with shellfish producers regarding growing areas and methods in California, Oregon and Washington. Developed shellfish certification standards for the west coast shellfish industry for the certification entity: "The Food Alliance". Maintains a coast-wide water quality monitoring related to ocean acidification, part of Northwest Association of Networked Ocean Observing Systems (NANOOS). Charged with the maintenance, deployment, and retrieval of a Sontek current meter, ISCO water samplers, YSI multiparameter dataloggers, pCO2 sensor package, Onset dataloggers, Honeywell meters and PSI developed dataloggers.

Experimental Biologist Aide, Oregon Department of Fish and Wildlife, Nehalem, OR, 1999
Conducted creel surveys of recreational salmon fishermen along the Nehalem river system.

Observer, Saltwater, National Marine Fisheries Service, Anchorage, AK, 1998-1999 Evaluated and enumerated the catch and by-catch of U.S. commercial pacific and black cod fishing vessels in the Bering Sea and Gulf of Alaska.

SELECTED PUBLICATIONS

Suhrbier, A. D., D.P. Cheney, M. E. Middleton, S. R. Booth, J. P. Davis. 2014. Examination of Farmed Geoduck (*Panopea Generosa* Gould, 1850) Predator Protection Efficacy and Environmental Effects, Journal of Shellfish Research, In press.

Cheney, D.P., Dewey, W.F., Suhrbier, A.D., Ferreira, J.G., Cordell, J.R., and J.P. Davis. 2012. Production and environmental effects of manila clam farming in North Puget Sound: Comparison of yields and responses of macrofauna to mechanical and hand harvest.

Abstracts: 104th Annual Meeting, National Shellfish Association, Seattle, WA. (abstract).

Suhrbier, A.D. 2012. Water quality monitoring at Washington State shellfish hatcheries and setting sites. *Abstracts*: 104th Annual Meeting, National Shellfish Association, Seattle, WA. (abstract).

SELECTED PRESENTATIONS

Vibrio Relay Update. PSCGA/NSA Annual Meeting. Bend, OR. October 2, 2013.

Cantwell Project Update: Water quality monitoring efforts at hatcheries and setting sites in Oregon and Washington (with Alan Barton, PCSGA). PSCGA/NSA Annual Meeting. Bend, OR. October 2, 2013.

Manila Clam Harvest Method Evaluation in Samish Bay, WA. PSCGA/NSA Annual Meeting. Tulalip, WA, September 26, 2012.

Appendix C: Pacific Shellfish Institute Company Overview

1. Name: Pacific Shellfish Institute
   DUNS: 948618624
   Address: 120 State Avenue NE #1056, Olympia, WA 98501
   Telephone: (360) 754-2741
   Fax: (360) 754-2246
   E-mail: psi@pacshell.org

2. Key Contact: Bobbi Hudson, Executive Director
   Address: 120 State Avenue NE #1056, Olympia, WA 98501
   Telephone: (360) 754-2741
   Fax: (360) 754-2246
   E-mail: bobbi@pacshell.org

3. Authorized person: Same as Key Contact (above)

4. The Pacific Shellfish Institute (PSI) is a Section 501(c)(3) private nonprofit organization whose mission is: "*Sustainable shellfish resources and healthy marine environment through research and education.*" PSI formed in 1995 to develop and disseminate scientific and technical information of value to the general public, shellfish farmers, and public officials in connection with shellfish-related environmental and animal/human health and safety issues. Current PSI research encompasses a broad range of biological, ecological, chemical and social science. Highlighted projects include investigations into the ecological impacts of mechanical clam harvest, *Vibrio parahaemolyticus* reduction strategies, ecological carrying capacity modeling, ocean acidification impacts on shellfish seed rearing, nutrient bioextraction studies, clam population surveys, and water quality monitoring for siting of new shellfish aquaculture infrastructure.

   PSI staff, including executive director Bobbi Hudson, senior scientists Dr. Daniel Cheney and Dr. Steven Booth, and senior biologist Andrew Suhrbier are familiar with the particular challenge of studying *Vibrio* in the field (e.g., identification of appropriate study sites, specialized sample collection and transport needs to avoid cross contamination, etc.). Furthermore, PSI has a long-standing relationship with the West Coast shellfish aquaculture industry, including Pacific Coast Shellfish Growers Association (PCSGA) members and staff. Recent and proposed PSI research features strong collaboration with both shellfish farmers and regulatory agencies, including the Washington Department of Health and FDA. If selected through this 2014 ISSC RFP, PSI would collaborate closely with these entities to complete proposed research.

5. PSI staff members and board of directors must abide by the established "Conflict of Interest Policy for the Pacific Shellfish Institute", which specifically states:

   "A conflict of interest is defined as an actual or perceived interest by a staff or Board member of the Pacific Shellfish Institute (PSI) in an action that results in, or has the appearance of resulting in, personal, organization, or professional gain. Officers and members are obligated to always act in the best interest of the organization. This obligation requires that any officer or member, in the performance of duties, seek only the furtherance of the organization's mission. At all times, officers and Board members are prohibited from using their job title or the organization's name or property, for private profit or benefit."

   Furthermore, the policy describes how conflicts of interest shall be resolved:

   "When a conflict of interest is relevant to a matter requiring action by the Board, the interested person(s) shall call it to the attention of the Board and said person(s) shall not vote on the matter. In addition, the person(s) shall not participate in the final decision or related deliberation regarding the matter under consideration. When there is a doubt as to whether a conflict exists, the matter shall be resolved by vote of the Board, excluding the person(s) concerning whose situation the doubt has arisen. The official minutes of the Board shall reflect that the conflict of interest was disclosed and the interested person(s) did not participate in the final discussion and did not vote on the matter."

Standard Operating Procedure
External Vibrio Technical Assistance and Research Requests

I. PURPOSE

The purpose of this standard operating procedure (SOP) is to standardize the process by which external requests for Vibrio related technical assistance and research are submitted, reviewed, prioritized, and granted. This SOP will not apply to internal FDA requests (e.g. ORA requests to CFSAN), routine technical assistance provided by Shellfish Specialists, or external requests which require only minimal CFSAN resources. This process is also not intended to supersede FDA's ability and willingness to respond to emergency situations and requests that arise due too such emergencies.

II. BACKGROUND

FDA receives numerous requests throughout the year from states, industry, and other stakeholders to provide training, technical assistance, and research on Vibrios. Requests have been made via official and unofficial channels, and FDA has made every attempt possible to accommodate all requests for assistance. This SOP serves to address the need to standardize how FDA responds to these requests to ensure that all requests are considered, thoroughly reviewed, prioritized, and appropriately responded to.

III. SUBMISSION OF REQUEST

External requests for Vibrio technical assistance and research must be submitted to FDA officially using the **External Vibrio Technical Assistance and Research Request Form** (Attachment I). The submitter must complete the request form in its entirety to ensure adequate review and prioritization. The request form will capture background information, categorize the nature of the request, and provide details

about leveraging resources of submitters, among other important information.

Submissions of requests will be received on an ongoing basis. However, any requests that require technical assistance or research during the Vibrio season (May - October) must be submitted no later than January 1 of that year.

Request forms must be submitted to the FDA Vibrio Assistance Review Board (VARB; see below) via the Regional Shellfish Specialist (RSS). The RSS will submit the request to the VARB Chair, and it is the Chair's responsibility to assign the request an official tracking number and notify the submitter via the RSS upon receipt.

IV. REQUEST REVIEW AND PRIORITIZATION

The VARB, an internal FDA committee, will be formed to review and prioritize external requests. Members of the board will be selected such that a range of expertise is available for each request review.

Within one week of receipt, the VARB Chair appoints a liaison from the board for each request. The liaison serves to represent the request through the review and prioritization process. If questions arise about the request, it is the responsibility of the liaison to communicate with the submitter and their RSS to resolve issues.

The VARB Chair and Vice-Chair will prepare a summary of the number and types of requests received. This summary will be distributed to the FDA National Shellfish Team, approximately one month prior to the VARB meeting.

The VARB will meet quarterly (the first week of February, May, August, and November), or ad hoc as needed, to review and prioritize requests. At least five VARB members must be present in order for the review and prioritization to proceed. Requests will be evaluated and ranked following the factors described in the **Request for Assistance: Evaluation Criteria** (Attachment II).

V. FDA APPROVAL

The VARB Chair will submit a summary of reviews and a prioritized list of requests to FDA/CFSAN/OFS/DSS and FDA/CFSAN/OFS/DSST managers within one week of the VARB meeting for review. Managers will review the VARB recommendations and inform the VARB Chair of concurrence or concerns within two weeks. If further discussion is needed, the VARB

Chair will coordinate a meeting between the VARB and OFS research and policy managers to reach an agreement on the requests to be supported.

VI. NOTIFICATION OF REQUEST OUTCOME

Once OFS management has determined which requests are approved, the VARB Chair will notify request submitters via the RSS of the outcome (generally within four weeks of VARB meeting). Submitters of requests that cannot be accommodated at that time will receive specific feedback on the reason(s) for rejection and will be provided the option to have the request retained for consideration in the next review cycle.

The VARB will complete a summary of evaluation rankings and outcomes. This summary will be distributed via the VARB Chair to the FDA National Shellfish Team and ISSC within one week of notifying the submitters of final decisions.

VII. ATTACHMENTS

Attachment I is the **External Vibrio Technical Assistance and Research Request Form**. Requests must be submitted on this form and in accordance with instructions to be considered.

Attachment II, **Request for Assistance: Evaluation Criteria**, describes the criteria to be considered for request evaluation and prioritization.

SUBMISSION FORM
External Vibrio Technical Assistance and Research Requests

I. Requestor Information

Name of requestor:	
Affiliation:	
Address:	
Phone:	
Email:	
Request subject/title:	
Date submitted:	

II. Nature of Request

Characterize the nature of your request. Check (√) all that apply.

- ☐ **Training/proficiency sampling**
- ☐ **Risk assessment consultation**
- ☐ **Demonstrations**
- ☐ **Method development/validation**
- ☐ **Reopening sample analysis**
- ☐ **Research project**
- ☐ **Other (describe)**

III. Description of Request

Please describe your specific request for Vibrio technical assistance or research. Be certain to include answers to the following questions:

1. Provide a brief description.

2. How will the request address needs or data gaps of the National Shellfish Sanitation Program?

3. When would the assistance from FDA occur?

4. What specific capabilities/capacities are being requested from FDA? This may include technical expertise, equipment, personnel time, and financial resources. If the request includes sample analysis by FDA, provide the anticipated number of samples and specific type of analysis requested (e.g., total and tdh+ *V. parahaemolyticus* by MPN-PCR). Be as specific as possible for resources requested (e.g., funds, anticipated number and time of personnel staff).

5. What specific capabilities/capacities are being provided by your organization? This may include technical expertise, equipment, personnel time, financial resources, and travel.

6. What resources will your organization be leveraging in support of this request? This may include funding, personnel time, laboratory supplies/reagents, and travel (e.g., working with academic laboratory to provide analytical support).

7. What is the practicality and applicability of the project? This includes the anticipated time to result(s), the adaptability to state/industry practices, and overall project expense.

8. How do you plan to maintain or expand the knowledge, expertise, and/or result(s) gained? Be specific in your plans for maintenance/expansion (e.g., results will be compiled with future years' data to understand the baseline Vp levels in the studied growing areas)

9. What would be the impact on the National Shellfish Sanitation Program of maintaining the status quo and not receiving the Vibrio technical assistance or research?

10. Is there any additional information that would be pertinent to the review of your request for Vibrio technical assistance or research?

REQUEST FOR ASSISTANCE: EVALUATION CRITERIA

The following criteria will be used to evaluate each Vibrio Technical Assistance and Research Request submission. Using these criteria, requests will be scored, prioritized, and a decision regarding support will be made.

I. Programmatic Impact

This criterion serves as a measure of the impact of the technical assistance or research. The degree to which the request addresses outstanding National Shellfish Sanitation Program (NSSP) needs or data gaps will be evaluated. This measure also takes into consideration the applicability to other states/regions. Requests that address data gaps associated with Interstate Shellfish Sanitation Conference (ISSC) proposals and/or recommendations of the ISSC Executive Board may receive higher priority.

II. FDA Capability & Capacity

This criterion evaluates the suitability and availability of FDA's capability/capacity as requested. The requestor must state the specific FDA capabilities/capacity desired in the submission form. FDA capability/capacity includes technical assistance expertise, research, equipment, personnel time, and financial resources. The review board will assess whether FDA has the specific requested capability/capacity that would result in the successful completion of the technical assistance or research request.

III. Requestor Capability & Capacity

This criterion evaluates the capability/capacity of the requesting organization(s) for completion of the request. Requestor capability/capacity includes infrastructure, expertise, equipment, personnel time, and financial resources. The requestor must state their specific capabilities/capacity for the board to determine whether the requestor is adequately set up to receive the requested technical or research assistance.

IV. Leveraged Resources of Requestor

This criterion evaluates the leveraged resources that will be provided by the requestor. The request submission must state how the requestor will leverage existing resources to conduct the proposed technical assistance

or research activities. Leveraged resources may include funding, personnel time, laboratory supplies/reagents, and travel. Requests that are submitted with resources leveraged by the requestor matching or exceeding those requested from FDA may receive higher priority.

V. Sustainability

This criterion evaluates the sustainability of the request's outcome(s). The request submission must state how the requestor plans to use, maintain or expand the knowledge, expertise, and/or result(s) gained by the technical assistance or research. Submissions that outline plans for not only use and sustainability, but also for passing on the technical assistance or research capabilities in the future, across their organization or to other organizations may receive higher priority.

National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish
Model Ordinance Interpretation Request

Model Ordinance Reference(s):	Chapter I Shellfish Sanitation Program @.02 Dealer Certification E. Interstate Certified Shellfish Shippers List (ICSSL). (1) When the Authority certifies a person to become a dealer, the Authority shall notify the FDA for the purpose of having the dealer listed in the ICSSL. The Authority shall include any permit designation to be included in the ICSSL. The notice shall be in the format of FDA Form 3038. **Designations:** **Certification** SP – Shucker Packer RP – Repacker SS – Shellstock Shipper RS – Reshipper DP – Depuration **Permit** PHP – Post Harvest Processing AQ – Aquaculture WS – Wet Storage (2) The Authority shall notify the FDA for the purpose of having the dealer removed from the ICSSL whenever a dealer's certificate or permit is: (a) Suspended; or (b) Revoked.
Question(s):	What certified shellfish dealers should have a PHP permit designation included with their listing in the ICSSL?
Interpretation:	Any certified shellfish dealer that conducts Post Harvest Processing within their facility, as well as dealers that have their product Post Harvest Processed at another PHP facility, shall be given the "Permit Designation" of "PHP" in the ICSSL.
Rationale:	The PHP permit designation is intended to provide ICSSL recognition to dealers that apply validated PHP technologies to their shellfish, either in their own facility or in another ICSSL designated PHP facility. It is not intended to recognize dealers who purchase for sale PHP product from another dealer. The list of dealers offering PHP product for sale could become extensive and would remove from the NSSP the intended incentive for dealers to apply PHP technologies to their own product.
Date Received:	
Party Responsible for Development of Draft:	Raymond Burditt/Paul DiStefano FDA/CFSAN Division of Seafood Shellfish and Aquaculture Policy Branch 5100 Paint Branch Parkway College Park, MD 20740

Public Health Practice Agreement between the Interstate Shellfish Sanitation Conference and the University of South Carolina Arnold School of Public Health

Student Name: James Howard Evans

Project Title: Vibrios, Coliphages and Molluscan Shellfish Seafood Safety: Analysis of Public Health and Environmental Data Related to Illnesses in Coastal States

Sponsoring Organization: The Interstate Shellfish Sanitation Conference (ISSC)

Faculty Advisor: Dr. Geoffrey I. Scott, Dept. of Env. Health Sciences, Arnold School of Public Health, University of South Carolina

Practicum Mentor: Mr. Ken Moore, Executive Director the Interstate Shellfish Sanitation Conference

1. Learning Objectives & Outcomes
Student will gain a technical and practical knowledge of Microbial Source Tracking (MST) (e.g. coliphages) and Vibrio infections in humans related to molluscan seafood consumption including:

1) **Geographical Information on Disease Outbreaks** – Gain familiarity with coastal estuary and watershed types, including tidal creeks, open water systems, riverine and closed systems and molluscan shellfish species involved in illnesses. Understand how estuary characteristics may relate to Vibrio levels in surface waters and molluscan shellfish and how MST indicators such as coliphages are affected.

2) Compilation of Existing Data from States– will work with the ISSC, FDA, NOAA, EPA and state shellfish control agencies to garner existing data on shellfish bed closures around the US. Information on disease outbreaks and illnesses in the US will be compiled and synthesized, with an emphasis on MST and Vibrio correlated.

3) Statistical Analysis of Data – Initially basic descriptive statistics (Mean, SD, SEM, etc.) will be generated along with more basic statistical programs of analysis, which help identify predictive variables (e. g. temperature, salinity, pH, and turbidity). Understand applicability of these variables to Vibrio prediction, modeling and forecasting to enhance public health protection. Also statistical analysis of related data on coliphages will be analyzed.

2. Work Tasks to be Performed by Student: The development of work tasks will be ongoing as it depends upon the timing and results of initial discussions among the ISSC members including federal and state agencies as well as shellfish industry and academia. These discussions will provide the framework and oversight for future data analysis

Specific Work Tasks to be performed by James Evans as part of this agreement with the ISSC include:

I. Prepare a written summary of our current state of knowledge on Vibrios and MST (e.g., coliphages) in coastal ecosystems including molluscan shellfish seafood. Include the different types of Vibrios but with a specific focus on *V. vulnificus* and *V. parahaemolyticus*. Include information on analytical detection methods for Vibrios and MST with an emphasis on predictive modeling capabilities for Vibrios and coliphages.

Standards: Develop a fundamental technical understanding of Vibrio related seafood safety issues and effectiveness/utility of MST Methods to predict seafood safety risk. Be able to analyze and explain results from literature reviews and statistical analysis. Complete within allotted time frame (June-August, 2014).

II. Compile and organize peer reviewed data and federal/state agency data on levels of Vibrios in the environment including information on the levels in seawater, sediments and molluscan shellfish. Compile data on different MST methods with an emphasis on coliphages.

Standards: Complete initial compilation of data by 15 August, 2014

III. Analyze compiled peer reviewed data and federal/state agency data on levels of Vibrios in the environment including information on the levels in seawater, sediments and molluscan shellfish. This would include basic descriptive statistics and regression modeling to identify predictive environmental variables that can be used to better understand causative, controllable and manageable environmental variables to reduce hazards of illness to human consumers. Also analyze existing MST data on coliphages and assess utility for protecting seafood consumer health.

Standards: Complete within allotted time frame (August- Sept., 2014) including time for editing). Work independently.

IV. Compile findings of Statistical Analysis and Literature Review into a Final Report focused on better identifying factors influencing human illnesses from Vibrios in molluscan shellfish with a specific focus on *V. vulnificus* and *V. parahaemolyticus* and on MST methods for coliphages and other innovative methods.

Standards: The final report should be well organized and will include Background, Methods, Results, Discussions and Conclusion sections, which are presented with narrative explanations and Tables/Figures explaining results and interpretation of parameters and data regarding Vibrio illnesses from seafood consumption and causative factors involved in shellfish mediated exposure. MST reporting will focus on the utility of different MST methods in assessing microbial hazards/risks in shellfish harvest areas. Satisfactorily coordinate and maintain contact between parties within the ISSC as the report is developed. Demonstrate the necessity of modifications to the report following feedback from state and federal agencies as well as industry and academia, as the report is reviewed. Final Report will be completed by December, 2014.

3. Experiences to be Undertaken: Student will work with Ken Moore and the ISSC staff and members of the ISSC to complete this analysis of Vibrio illnesses and evaluation of important environmental factors affecting human illness. Student will be working in the ISSC Executive Offices in Columbia, SC. He will be using the ISSC's resources as to compile a technical report analyzing information on molluscan shellfish illnesses in the US.

4. Criteria for Assessment of Learning Results and Work Performance: Successful completion of Tasks I-V listed above, including development of a work plan and timeline/schedule for completion of all tasks, including data analysis and interpretation. Final Report will report in time allotted for practicum (June 3, 2014 - December 15, 2014). Practicum report and oral defense will take place shortly after this period in January- February, 2015, pending scheduling with committee members.

5. Detail any Special Conditions, Arrangements or Restrictions: James H. Evans will work on all aspects of this project, scheduled for June- December, 2014. Student may occasionally need to shift hours from one day of the week to another depending upon circumstances, but advance notice should be given to the ISSC and Practicum Advisor, if this is required. During the semester he will generally work more

than 10-20 hours during the week depending upon the academic calendar (Summer School versus Fall Semester).

6. Time Sequence for Stated Results: Student will work 10-20 hours per week during the summer, 2014 semester, at times determined by the Sponsor. Student will work 10-15 hours per week during the fall, 2014 semester, at times determined by the Sponsor. James will receive a total of 6 hours of course credit during the summer and fall 2014 semesters.

Monitoring of Project Progress.

Time Line for Project indicated below:

Date	**Activity**
06/14	Initial scoping meeting with ISSC for the Project and Initiate Project
06-08/14	Complete Literature Review (Task 1) and begin Compilation of Data (Task 2) from ISSC members. ***(Summer Semester Grading)***
07-10/14	Complete Compilation of Data (Task 2) and Statistical Analysis of Data (Task 3)
10-12/14	Completion of Statistical Data Analysis (Task 3) and Drafting of Draft and Final Reports (Task 4) ***(Fall Semester Grading)***
01-02/15	Oral Defense of Project

UNIVERSITY OF SOUTH CAROLINA

OFFICE OF THE CHAIR
DEPARTMENT OF ENVIRONMENTAL HEALTH SCIENCES
ARNOLD SCHOOL OF PUBLIC HEALTH

Mr. Ken Moore, Executive Director,
Interstate Shellfish Sanitation Conference
2009 Dawson Road, Suite 2
Columbia, SC 29223

7 August, 2014

SUBJECT: Request for Involvement in the Interstate Shellfish Sanitation Conference (ISSC) Mandatory Harvester and Dealer Continuing Education Training Program

Dear Ken;

Following our phone conversation today, I am glad to be involved in the ISSC Mandatory Harvester and Dealer Continuing Education Training Program, as I see this may provide some outstanding opportunities for us to build upon our current Student Practicum Program as part of our Masters in Public Health (MPH) Degree Program within the Arnold School of Public Health. The ISSC requirement for this training program was approved for licensure of harvester and dealers in all relevant states. At the 2011 Biennial Meeting, a mandatory harvester and dealer continuing education requirement was approved for licensure of harvester and dealers in all relevant states. That requirement was enacted on January 1, 2014, and those states without a continuing education program are currently out of compliance with the National Shellfish Sanitation Program (NSSP) guidelines.

To date, several of the states have developed their own stand-alone programs, but in general, most states have not developed a program and only a handful are at the stage of implementing a program to meet this requirement. The ISSC, working with the University of Florida, has developed a training course that will meet the NSSP guidelines for this training (using Articulate Storyline software). The ISSC has developed a template for distribution to states for their use in developing programs that will meet the harvester and dealer training program requirements. However, many of the states are not in a position to purchase this software or have personnel that are trained in using the software to manipulate the templates such that they can develop a program that is applicable to their state. This is where I believe

where we at USC can assist the ISSC as my expertise in shellfish issues and educational training can assist the ISSC in program implementation. We have additional faculty and staff who may be able to assist the ISSC in this effort as it will provide excellent opportunities for additional graduate students to be involved with the ISSC.

The templates, as currently designed, have a great deal of valuable information related to shellfish harvesting and handling, along with information about microbial, chemical, and other contaminants. These templates will be the basis of a national training program required by NSSP guidelines. This program and the information therein will be used across the country and will target shellfish industry personnel (harvesters and dealers).

I look forward to interacting with you and your staff as your staff to help implement this program and to review the success of the program. Given our involvement at USC, we will need to assist you with the software purchase to assure that we have copies for our students, staff and faculty as we expand the knowledge of our faculty, staff and students in its use and provide assistance to the ISSC.

We look forward to this interaction with the ISSC and as we discussed I think it would be a good idea to develop a formal MOU for future interactions such as this to make this easier for us to do. Thank you for this opportunity to interact with the ISSC. Please feel free to contact me at the above address, email (giscott@mailbox.sc.edu) or phone (803/777-8964) if clarification or further information is required and I look forward to the implementation of this program.

Sincerely;

Geoffrey I. Scott, PhD.,

Clinical Professor and Chair
Department of Environmental Health Sciences'
Arnold School of Public Health
University of South Carolina

ISSC

Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223-1740

July 7, 2014

Kevin Smith
CFSAN
5100 Paint Branch Parkway
College Park, MD 20740

Lori LeMaster
CFP Conference Chair
TN Department of Health
Environmental Health
Andrew Johnson Tower, 4th Floor
Nashville, TN 37234

Dear Kevin Smith and Lori LeMaster

The Interstate Shellfish Sanitation Conference (ISSC) has reviewed the Conference for Food Protection (CFP) action on Issue I-025 and offers the following comments for consideration by the CFP and the USFDA.

The background information included in the Public Health Significance of the Issue is misleading. Recent increases in Vibrio illnesses are not at all related to *Vibrio vulnificus (V.v.)*. The increases are associated with the spread of O4:K12 and O4:Kuntypeable strains of *Vibrio parahaemolyticus (V.p.)*. Historically these strains have caused illnesses in the Pacific northwest, but recently, illnesses have begun to occur on the northeast coast of the United States. The risk of death associated with *V.p.* is overstated. Death from *V.p.* is extremely rare. The rate of illness associated with *V.v,* the species associated with severe illness and death, has not increased and remains stable at approximately 35 illnesses annually.

The ISSC supports the use of consumer advisories and welcomes efforts to improve their effectiveness. However, the ISSC does not agree that the recommended solution of Issue I-025 would improve effectiveness or reduce illnesses.

The ISSC is continuing to focus efforts to better understand the virulent strains of V.p. associated with recent increases in illnesses. The risk of *V.p.* illnesses associated with these virulent strains appears to be a regional problem. There are harvest regions of the U.S. that have not been the source of shellfish associated with increases in reported illnesses. Additionally, the language does not recognize that the risk level is not constant throughout the year. At lower water temperatures the risk of *V.p.* illness greatly diminishes. The proposed language would not be helpful to consumers in identifying raw shellfish that actually pose a higher risk of illness. Additionally, the proposed burden for providing proof of post-harvest processing (PHP) in Section E. is not necessary. Presently the FDA Interstate Certified Shellfish Shippers List (ICSSL) contains the relevant information and shellfish that have been PHP treated are labeled as such. The reference for the analytical method is also inaccurate.

The recommended solution assumes that the relative risk of consumption of raw shellfish is much higher than other animal foods that are consumed raw, undercooked, or not otherwise processed to eliminate pathogens. The recommended solution in the Issue is not the most appropriate way to address relative risk.

Phone 803-788-755 Email issc@issc.org Fax 803-788-7576

The ISSC recommends that the CFP take no action on Issue I-025 as written. The CFP is encouraged to continue to pursue steps to improve the effectiveness of consumer advisory and compliance with existing temperature control, handling and record keeping requirements at retail and food service establishments. The ISSC offers its assistance in any way that you think appropriate.

Sincerely,

Maryanne Guichard
Executive Board Chair

/nsd/ccm

cc: ISSC Executive Board
David McSwane, CFP Executive Director
Paul DiStefano, USFDA

Original Issue- 1-025

Title

Consumer Advisory - Amend Section 3-603.11

Issue you would like the Conference to consider

The FDA Food Code recognizes that consumers should have notice regarding the risk of foodborne illness from raw or undercooked meats, poultry, seafood, shellfish, or eggs. However, the consumer advisory fails to provide adequate notice for persons to accurately assess the risk of severe illness and death from pathogenic *Vibrio* bacteria in raw oysters.

Public Health Significance

FoodNet data indicates that *Vibrio* illnesses have more than doubled while illnesses from all other major foodborne pathogens have either been stable or decreased. There is also evidence that serious pathogenic *Vibrio* species are becoming more common in raw shellfish. *Vibrio vulnificus* in raw oysters harvested from the Gulf of Mexico has long posed a well-defined risk of severe illness and death to consumers with compromised immune systems, liver damage, diabetes, the genetic disorder hemochromatosis, and certain gastric disorders. In recent years, a number of *V. vulnificus* cases are associated with oysters harvested along the East Coast. *Vibrio parahaemolyticus* is associated with mild gastroenteritis in persons with healthy immune systems, and can progress to life-threatening infections in persons with pre-existing medical conditions. In 2012, a highly virulent West Coast strain of *V. parahaemolyticus* appeared in East Coast oysters causing the largest oyster-associated outbreak ever recorded along the Atlantic Coast. Outbreaks in 2013 far exceed the count of cases from 2012. Given the increasing number of illnesses and the spread of pathogenic strains to new areas, it is critical that persons have adequate notice of the risk so that they will seek early medical care and inform their doctor they have eaten raw oysters. While the strongest prevention is to require all oysters shipped interstate to be treated post-harvest to eliminate the pathogen, the industry has resisted such requirements. The proposed warning is, therefore, consistent with industry preferences for consumer education in lieu of other controls. It is a critical requirement because other than self-identification, food establishments have no way of recognizing at-risk patrons. To the extent that patrons have adequate information about their own health status, the warnings may reduce the number of illnesses and deaths (with the attendant bad publicity associated with news reports and lawsuits). Additionally, since consumer perceptions can alter choices thus reducing demand, industry interests and public health walk hand-in-hand with providing adequate notice that allows at-risk populations to understand and assess the danger of consuming raw oysters.

Recommended Solution: The Conference recommends...

that a letter be sent to the FDA recommending the 2013 Food Code be amended with the addition of new consumer advisory language to Section 3-603.11, as follows (new language in underline format):

Section 3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens

(D) Every FOOD ESTABLISHMENT that offers raw oysters shall provide a written warning to any person who orders raw oysters, stating:

WARNING

THIS FACILITY OFFERS RAW OYSTERS. EATING THESE OYSTERS MAY CAUSE SEVERE ILLNESS AND EVEN DEATH IN PERSONS WHO HAVE LIVER DISEASE, CANCER, DIABETES, OR OTHER CHRONIC ILLNESSES THAT WEAKEN THE IMMUNE SYSTEM. If you eat raw oysters and become ill, you should seek immediate medical attention. If you are unsure if you are at risk, you should consult your physician.

(E) Warnings under subsection (D) are not required whenever the FOOD ESTABLISHMENT has received a copy of a current verification letter from the dealer and tags or labels are as required by Section 3-202.18 of this Code demonstrating that the oysters have been subjected to an oyster treatment process sufficient to reduce Vibrio bacteria to an undetectable level, as defined in the U.S. Food and Drug Administration Bacteriological Analytical Manual, 2004 Edition.

Attachments

- "Public Health Rationale Raw Oysters" (2013)
- "Increase in Vibrio Illnesses-- CDC" (2013)

Submitter Information

Name	Sarah Klein
Organization	Center for Science in the Public Interest
Address	1220 L St NW #300 Washington, WA 20005
Telephone	202-777-8339
Fax	
Email	sklein@cspinet.org

Word File

- File with Tracking

Printing Options

- Print Issue
- Print All Attachments
- Print Issue and Attachments

2792 Miramar Lane, Lincoln, CA 95648 | Privacy Policy | Terms & Conditions | About Us | Contact Us

Proposal Subject: *Panopea generosa* as Species Exempted from Shellstock Storage Critical Control 'Point

Specific NSSP Guide Reference: NSSP Guide Section II. Model Ordinance
Chapter XIII. Shellstock Shipping .01 Critical Control Points
C. Shellstock Storage Critical Control Point - Critical Limits.

Text of Proposal/ Requested Action Product intended for relay, wet storage, depuration, *mercenaria spp*. which is being cooled utilizing an Authority approved tempering plan, or geoduck clams (*Panopea generosa*) are exempt from the requirements listed above in .01.B.(4) with implementation beginning January 1 after proposal adoption.

Public Health Significance: The geoduck clam (*Panopea generosa* – until 2010 referred to by the extinct clam name of *Panopea abrupta*) is a fishery dominated by the native tribes in Washington. The optimum handling, keeping and shipping temperature is 47° to 52° Fahrenheit (8.3°-11.1° Celsius). The lower temperatures contained in the shellstock critical control point at Chapter XIII. @.01.B. (4) would cause significant mortality in this product. There is no record of geoduck clams being associated with Vibriosis; laboratory testing of geoduck clams in 2007 by DOH revealed no detected presence of *Vibrio parahaemolyticus*.

Cost Information (if available): There is no projected cost for this proposal. There is expected cost savings associated with this proposal due to the high loss of product expected with compliance.

Action by 2013 Task Force II Recommended adoption of Proposal 13-216 as substituted.

(5) Product intended for relay, wet storage, or depuration, or either geoduck clams (*Panopea generosa*), or *Mercenaria sp* which are being cooled utilizing an Authority approved tempering plan are exempt from the requirement listed above in .01 B. (4) above.**[C]**

Implementation is to begin three (3) months after concurrence by FDA. This achieves the goal of not waiting until publication of the new NSSP Guide and takes into account the requirement that FDA approve all changes adopted at the ISSC Biennial Meeting, while minimizing unnecessary loss of geoduck product.

Substitute Public Health Significance
The geoduck clam (*Panopea generosa*) was until 2010, referred to by the extinct clam name of *Panopea abrupta*. The optimum handling, keeping and shipping temperature is 47° to 52° Fahrenheit (8.3°-11.1° Celsius). The lower temperatures contained in the shellstock critical control point at Chapter XIII. .01. B. (4) would cause significant mortality in this product.

Action by 2013 General Assembly Adopted recommendation of 2013Task Force II on Proposal 13-216.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-216.

ISSC

Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223-1740

July 30, 2014

Division of Docket Management
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852:

Docket No. FDA-2013-N-0013
RIN 0910-AG98
Agency: Food and Drug Administration
Parent Agency: Department of Health and Human Services

Dear Sir or Madam:

The Interstate Shellfish Conference (ISSC) appreciates the opportunity to provide comment on the USFDA proposed rule for Sanitary Transportation of Human and Animal Food. The ISSC was formed in 1982 to foster and promote shellfish sanitation through the cooperation of State and Federal control authorities, the shellfish industry, and the academic community. The ISSC recognizes the importance of temperature control of raw molluscan shellfish for minimizing post-harvest growth of bacteria. The National Shellfish Sanitation Program (NSSP) has specifically incorporated temperature controls to address the risk of illness associated with naturally occurring Vibrios.

The proposed regulations are consistent with the efforts of the ISSC through the NSSP to address temperature control of raw molluscan shellfish. Presently, the NSSP does not attempt to regulate carriers directly. The points of enforcement of temperature controls in the program focus on shipping and receiving. These controls are primarily Hazard Analysis and Critical Control Point (HACCP) controls. As a result of State jurisdictional issues, direct regulation of carriers has not occurred in the program. This rule as proposed should serve to enhance temperature compliance with the existing NSSP requirements during shipments of raw molluscan shellfish.

In reviewing the proposed rule the ISSC offers three (3) specific comments as follows:

1. The language of the rule indicates an exception for live food animals. The ISSC requests that raw molluscan shellfish not be considered a live food animal under this proposed regulation.

2. The proposed regulation defines non-covered business as a shipper, receiver, or carrier engaged in transportation that has less than $500,000.00 in total annual sales. You

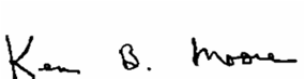
Phone 803-788-7559 Email issc@issc.org Fax 803-788-7576

indicate that 97% of the food industry will be covered. This suggests that only 3% of food industry business have sales less than $500,000.00. This may not be true of the US shellfish industry which is comprised of mostly smaller companies.

3. Section H.3. includes potential waivers for companies with valid permits that are inspected under the National Conference on Interstate Milk Shipments and Food Establishments holding valid permits when engaged in certain types of operations. These potential waivers should be extended to shippers, carriers, and receivers of shellfish that hold valid State permits.

Thank you for considering these comments. We look forward to working with the USFDA to improve the safety of raw molluscan shellfish.

Sincerely,



Ken B. Moore
Executive Director

/ccm

Phone 803-788-7559 Email issc@issc.org Fax 803-788-7576

General Provisions

1. Except for non-covered businesses as defined in § 1.904, the requirements of this subpart apply to shippers, receivers, and carriers engaged in transportation operations whether or not the food is being offered for or enters interstate commerce.

2. The failure by a shipper, carrier by motor vehicle or rail vehicle, or receiver engaged in transportation operations to comply with the requirements of this subpart is a prohibited act under section 301(hh) of the Federal Food, Drug, and Cosmetic Act (**21 U.S.C. 331**(hh)).

3. *Carrier* means a person who owns, leases, or is otherwise ultimately responsible for the use of a motor vehicle or rail vehicle to transport food. The carrier is responsible for all functions assigned to a carrier in this subpart even if they are performed by other persons, such as a driver that is employed or contracted by a trucking firm. A carrier may also be a receiver or a shipper if the person also performs the functions of those respective persons as defined in this subpart.

4. *Farm* means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes facilities that pack or hold food, regardless of whether all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership.

5. *Food* means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. *Food* includes animal food and food also subject to the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

6. *Receiver* means any person who receives food after transportation, whether or not that person represents the final point of receipt for the food. A receiver may also be a carrier or a shipper if the person also performs those functions as defined in this subpart. A receiver does not include an individual consumer or a person who receives or holds food on behalf of an individual consumer and who is not also a party to the transaction and who is not in the business of distributing food.

7. *Shipper* means a person who initiates a shipment of food by motor vehicle or rail vehicle. The shipper is responsible for all functions assigned to a shipper in this subpart even if they are performed by other persons, such as a person who only holds food and physically transfers it onto a vehicle arranged for by the shipper. A shipper may also be a carrier or a receiver if the shipper also performs those functions as defined in this subpart.

8. *Time/temperature control for safety (TCS) Food* means a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation.

9. *Transportation equipment* means equipment used in food transportation operations, other than vehicles, e.g., bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems and unloading systems. Transportation equipment also includes a railcar

Vehicles and Transportation Equipment

10. Vehicles and transportation equipment used in transportation operations must be so designed and maintained in such a sanitary condition as to prevent the food they transport from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations.

11. Vehicles and transportation equipment that are used in transportation operations for food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation must be designed, maintained, and equipped, to maintain the food under temperature conditions that will prevent the rapid growth of undesirable microorganisms.

12. Each freezer and mechanically refrigerated cold storage compartment in vehicles or transportation equipment used in transportation operations for food that can support the rapid growth of microorganisms must be equipped with an indicating thermometer, temperature-measuring device, or temperature-recording device installed to show the temperature accurately within the compartment.

13. Vehicles and transportation equipment must be stored in a manner as to prevent the vehicles or transportation equipment from harboring pests or becoming contaminated in any other manner that could result in food for which they will be used becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations.

Transportation Operations

14. *General requirements.*

(1) Unless stated otherwise in this section, the requirements of this section apply to all shippers, carriers, and receivers engaged in transportation operations.

(2) All transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations, including:

- Taking effective measures such as segregation or isolation to protect food from contamination by raw foods and non-food items in the same load.
- Taking effective measures such as segregation, isolation, or other protective measures such as hand washing, to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations.
- For food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation, ensuring that the food is transported in a manner, including the temperature conditions, such that the transportation operation meets the requirements of paragraph (a)(3) of this section.

15. *Requirements applicable to shippers engaged in transportation operations.*

(1) The shipper must specify to the carrier, in writing, all necessary sanitary requirements for the carrier's vehicle and transportation equipment, including any specific design requirements and cleaning procedures to ensure that the vehicle is in appropriate sanitary condition for the transportation of the food, e.g., that will prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during the transportation operation. The information submitted by the shipper to the carrier is subject to the records requirements in § 1.912(a).

(2) Before loading food not completely enclosed by a container onto a vehicle provided by a carrier or into transportation equipment provided by a carrier, the shipper must visually inspect the vehicle or the transportation equipment provided by the carrier for cleanliness.

(3) A shipper of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation, whether a TCS food or a non-TCS food, must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, the temperature conditions necessary during the transportation operation, including the pre-cooling phase, to ensure that the operation will maintain the temperature conditions and meet the requirements of paragraph (a)(3) of this section.

(4) Before loading food, a shipper of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation, must verify that each freezer and mechanically refrigerated cold storage compartment or container has been pre-cooled in accordance with information submitted by the shipper as required by paragraph (b)(3) of this section.

16. A carrier:

(1) Must, once the transportation operation is complete, demonstrate to the shipper and if requested, to the receiver, that it has maintained temperature conditions during the transportation operation consistent with those specified by the shipper in accordance with § 1.908(b)(3). Such demonstration may be accomplished by any appropriate means agreeable to the carrier and shipper such as the carrier presenting printouts of a time/temperature recording device or a log of temperature measurements taken at various times during the shipment.

(2) Is not subject to the requirement of paragraph (d)(2)(i) of this section if the carrier and shipper agree in writing, before transportation operations, that the shipper is responsible for monitoring the temperature conditions during the transportation operation or otherwise ensuring that the food was held under acceptable temperature conditions during the transportation operation. The carrier must provide the written agreement to the receiver, if requested. The written agreement is subject to the records requirements of § 1.912(b).

(3) Before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for use for the transportation of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control, a carrier must pre-cool each

mechanically refrigerated freezer and cold storage compartment as specified by the shipper in accordance with paragraph (b)(3) of this section.

(4) A carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the three previous cargoes transported in the vehicle. The shipper and carrier may agree in writing that the carrier will provide information that identifies fewer than three previous cargoes or that the carrier need not provide any such information if procedures have been established that would ensure that the bulk vehicle offered will be adequate for the intended transportation operation, e.g., if the carrier by contract, will only offer vehicles dedicated to hauling a single type of product. The written agreement is subject to the records requirements of § 1.912(b).

(5) A carrier that offers a bulk vehicle for food transportation must provide information to the shipper that describes the most recent cleaning of the bulk vehicle, except that a shipper and carrier may agree in writing that the carrier need not provide any such information, if the carrier follows procedures that would ensure that the bulk vehicle offered will be adequate for the intended transportation operation, e.g., if the carrier has contractually agreed to use a specified cleaning procedure at specified intervals or if the shipper cleans the vehicle at his own facility. The written agreement is subject to the records requirements of § 1.912(b).

Records

17. Shippers must retain records that demonstrate that they provide information to carriers as required by § 1.908(b)(1) and (3) as a regular part of their transportation operations for a period of 12 months beyond when the shipper is subject to any requirement to provide such information.

UNITED STATES DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
NATIONAL MARINE FISHERIES SERVICE
GREATER ATLANTIC REGIONAL FISHERIES OFFICE
55 Great Republic Drive
Gloucester, MA 01930-2276

Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223

RE: Proposed Rule to Lift the Northern Temporary Paralytic Shellfish Poisoning Closure for Bivalve Harvesting

NOAA Fisheries Service is proposing to lift the Northern Temporary Paralytic Shellfish Poisoning (PSP) Closure for bivalve harvesting. We are taking this action at the request of the U.S. Food and Drug Administration (FDA) based on the premise that the area has not been subject to a toxic algal bloom for several years and testing of bivalve shellfish has demonstrated toxin levels well below those known to cause human illness. In addition, the FDA has developed an agreement with the Commonwealth of Massachusetts Division of Marine Fisheries (DMF) to conduct PSP monitoring of bivalves from the area in accordance with specified testing procedures. If we lift the closure, DMF will test the reopened waters and if the results yield samples that exceed the threshold for public safety, DMF would notify us, and we would work with the FDA to reinstate the closure.

Please note that this regulatory action would leave the area closed to the harvest of whole/roe-on scallops and gastropods.

A copy of the Federal Register notice is attached for your review, along with a copy of the letter from DMF to the FDA regarding the monitoring program. The comment period for this proposed rule ends on July 22, 2014. If you have any questions regarding this action, please contact Jason Berthiaume, Fishery Management Specialist, at 978-281-9177 or Jason.Berthiaume@noaa.gov.

Sincerely,

John K. Bullard
Regional Administrator

Enclosure

JUL 1 1 2014