



Interstate Shellfish Sanitation Conference

REQUEST FOR PROPOSAL

Techniques and Practices for
Vibrio Reduction

and

Techniques and Tools for
Toxin Management

April 29, 2020

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BACKGROUND

Human illnesses associated with the consumption of raw molluscan shellfish are of constant and significant concern to the Interstate Shellfish Sanitation Conference (ISSC). Over the past several decades the ISSC, States, and the US Food and Drug Administration (USFDA) have devoted significant resources to reduce foodborne illness from all sources. There are two primary illness concerns associated with shellfish consumption. They are:

- 1) naturally occurring vibrios
- 2) naturally occurring toxins.

The Center for Disease Control (CDC) data shows that the national incidence of illnesses from *Vibrio parahaemolyticus* (*V.p.*) has increased in recent years. While the ISSC has established controls for *V.p.*, it has been extremely difficult to fully assess the effectiveness of those controls. In recent years, the prevalence of naturally occurring toxins has increased. The types of toxins that cause human intoxication have increased as well as the regional distribution of these toxins.

The safety of raw molluscan shellfish for human consumption is primarily controlled in accordance with the sanitary measures of the National Shellfish Sanitation Program (NSSP). The NSSP was initially developed to protect consumers against enteric pathogens associated with fecal contamination of the waters from which they are harvested, in particular human fecal waste. Because *V.p.* and naturally occurring toxins occur naturally and are not associated with fecal pollution, initial NSSP controls did not offer a strategy for controlling these potential health concerns.

NATURALLY OCCURRING VIBRIOS

The current vibrio strategies of the NSSP require States to develop and implement controls necessary to reduce the incidence of illness associated with raw oyster and hard clam consumption. Current efforts by States to reduce the incidence of illness are primarily focused on promulgation of mandatory time from harvest to refrigeration requirements, the time from refrigeration to an internal temperature requirements, the maintenance of temperature control during transportation, and encouraging the use of post-harvest processing (PHP) technologies for reducing vibrio levels. Identifying the factors which affect risk of vibrio has proven to be difficult. The ISSC is focusing efforts to better understand the virulent strains of vibrio associated with recent illnesses and identify strategies for identifying and reducing the risk posed by these virulent strains.

NATURALLY OCCURRING TOXINS

In recent years, the number of identified naturally occurring toxins with the ability to cause human intoxication and illness has grown. In most cases, the techniques and methods for identification are very expensive and time consuming. The regulatory response for opening and closing could be improved by more precise, less expensive, and less time consuming testing techniques and methods.

PURPOSE OF THE REQUEST FOR PROPOSAL

The ISSC is seeking to fund studies to identify and evaluate factors which contribute to risk of vibrio illnesses and better tools for addressing biotoxin concerns. The purpose of this RFP is to invite interested parties to propose studies that could offer viable control options for identifying risk factors for vibrios and more effective techniques and tools for assessing risk from shellfish toxins. The ability to initiate data gathering in 2020 will be considered in the process. The remainder of this document provides additional information that will allow proposal submitters to understand the scope of the RFP and develop a proposal in an acceptable format.

SCOPE OF WORK

The following information should be considered by the submitter in developing proposals for the topics below.

I. Techniques and practices for Vibrio Reduction

The submitter should be familiar with the health risk posed by vibrios and have an understanding of post-harvest handling techniques that have the potential to reduce the risk of illness. Submitters are requested to consider total *V.v.* and *V.p.* in the development of a proposal with a focus on the most virulent strains.

A. The following activities have been prioritized for funding.

- (1) Evaluate environmental factors such as temperature, salinity, sediment type, etc. which could be controlling distribution, occurrence, and prevalence of total and pathogenic strains of vibrios.
- (2) Assess the environmental factors that influence growth and distribution of pathogenic strains of vibrios.
- (3) Development of methods for detection of pathogenic vibrios that are faster, less expensive and more sensitive.
- (4) Evaluate impact of various culture and harvest practices on levels of pathogenic vibrios in oysters following harvest. Analytical comparison of the various culture and harvest practices studied should include strategies for determining the risk indicators.
- (5) Collect and compile vibrio information that could be used to update risk assessments for *V.p.* and *V.v.* to address regional differences, consumption patterns, dose-response, influence of local environmental conditions, etc.

II. Techniques and Practices for Toxin Management

The submitter should be familiar with the health risk posed by naturally occurring toxins. With regard to naturally occurring toxins the submitter should have an understanding of the

known toxins which are identified in the NSSP and the tool and techniques that are necessary to manage the shellfish growing area when these toxins are present or have the potential to be present.

A. The following activities have been prioritized for funding.

- (1) Development of screening methods, qualitative or semi-qualitative, for the detection of toxins that are field deployable, inexpensive, and more rapid.
- (2) Development of tools for the identification of toxin-producing algal species and a better understanding of the factors influencing toxin production and shellfish uptake/depuration dynamics. (For example, what species are producing okadaic acid, dinophysis toxins and related toxins in regions where DSP has been detected?)

TECHNICAL CONTACT

Any questions concerning technical specifications or Statement of Work (SOW) requirements must be directed to:

Name	Keith Skiles, Assistant Executive Director
Affiliation	Interstate Shellfish Sanitation Conference
Address	209-1 Dawson Road, Columbia, SC 29223-1740
Phone	803-788-7559
FAX	803-788-7576
Email	issc@issc.org

CONTRACTUAL CONTACT

Any questions regarding contractual terms and conditions or proposal format must be directed to:

Name	Keith Skiles, Assistant Executive Director
Affiliation	Interstate Shellfish Sanitation Conference
Address	209-1 Dawson Road, Columbia, SC 29223-1740
Phone	803-788-7559
FAX	803-788-7576
Email	issc@issc.org

DUE DATE

A written confirmation of the Submitter's intent to respond to this RFP is required by 5:00 PM (EDST) on May 6, 2020. All proposals are due by 12:00 Noon (EDST) on May 20, 2020. Any proposal received at the designated location after the required time and date specified for receipt shall be considered late and non-responsive. Any late proposals will not be evaluated for award.

SCHEDULE OF EVENTS

Event	Date
1. RFP Distribution to Submitters	April 29, 2020
2. Written Confirmation of Submitters with Bid Intention	May 6, 2020 5:00 PM (EDST)
3. Proposal Due Date	May 20, 2020 12:00 Noon (EDST)
4. Target Date for Review of Proposals	May 27, 2020
5. Anticipated Decision and Selection of Submitter	June 3, 2020
6. Project Completion Date	September 1, 2021

PROPOSAL SUBMISSION

Award of the contract resulting from this RFP will be based upon the most responsive proposal submitters whose offer will be the most advantageous to ISSC in terms of cost, functionality, and other factors as specified elsewhere in this RFP. Preference will be given to submitters offering to match ISSC funding support. The ISSC is encouraging one to one matching funds.

ISSC reserves the right to:

1. Reject any or all offers and discontinue this RFP process without obligation or liability to any potential Submitter;
2. Accept other than the lowest priced offer;
3. Award a contract on the basis of initial offers received, without discussions or requests for best and final offers; and
4. Award more than one contract.

Submitter's proposal shall be submitted in several parts as set forth below. The Submitter will confine its submission to those matters sufficient to define its proposal and to provide an adequate basis for ISSC's evaluation of the Submitter's proposal.

To address the needs of this procurement, ISSC encourages Submitters to work cooperatively in presenting integrated solutions.

Submitter's proposal in response to this RFP will be incorporated into the final contract between ISSC and the selected Submitter. The submitted proposals are suggested to include each of the following sections:

1. Executive Summary
2. Approach and Methodology
3. Project Deliverables
4. Project Management Approach
5. Detailed and Itemized Pricing
6. Appendix: References
7. Appendix: Project Team Staffing
8. Appendix: Company Overview

The detailed requirements for each of the above-mentioned sections are outlined below.

EXECUTIVE SUMMARY

This section will present a high-level synopsis of the Submitter's response to the RFP. The Executive Summary should be a brief overview of the proposed study and should identify the main features and benefits of the proposed work.

SCOPE, APPROACH, AND METHODOLOGY

Include detailed testing procedures and technical expertise by phase. This section should include a description of each major type of work being requested of the Submitter. All information that is provided will be held in strict confidence.

PROJECT MANAGEMENT APPROACH

Include the method and approach used to manage the overall project and client correspondence. Briefly describe how the engagement proceeds from beginning to end.

DETAILED AND ITEMIZED BUDGET

Submitter to insert

NOTE: *The ISSC by policy does not pay overhead or indirect costs.*

APPENDIX REFERENCES

Provide three current references for which you have performed similar work.

APPENDIX PROJECT TEAM STAFFING

Include biographies and relevant experience of key staff and management personnel. Describe the qualifications and relevant experience of the types of staff that would be assigned to this project by providing biographies for those staff members. Describe bonding process and coverage levels of employees. Affirm that no employees working on the engagement have ever been convicted of a felony.

APPENDIX: COMPANY OVERVIEW

Provide the following for your company:

1. Official registered name (Corporate, D.B.A., Partnership, etc.), Dun & Bradstreet Number, Primary and secondary SIC numbers, address, main telephone number, toll-free numbers, and facsimile numbers.
2. Key contact name, title, address (if different from above address), direct telephone and fax numbers.
3. Person authorized to contractually bind the organization for any proposal against this RFP.
4. Brief history, including year established and number of years your company has been offering Information Security Testing.
5. The Submitter shall describe its existing system for identifying conflicts of interest. The Submitter shall also identify any conflicts of interest which may arise and shall describe how it proposes to resolve such conflicts.

AWARD CRITERIA

Any award to be made pursuant to this RFP will be based upon the proposal with appropriate consideration given to operational, technical, cost, and management requirements. Evaluation of offers will be based upon the Submitter's responsiveness to the RFP and the total price quoted for all items covered by the RFP.

The following elements will be the primary considerations in evaluating all submitted proposals and in the selection of a Submitter or Submitters:

1. Completion of all required responses in the correct format.
2. The extent to which Submitter's proposed solution fulfills ISSC's stated requirements as set out in this RFP.
3. An assessment of the Submitter's ability to deliver the indicated service in accordance with the specifications set out in this RFP.
4. The Submitter's experiences and record of past performance in delivering such services.
5. Availability of sufficient high quality Submitter's personnel with the required skills and experience for the specific approach proposed.
6. Overall cost of Submitter's proposal to include a matching requirement of at least 50%.

ISSC may, at their discretion and without explanation to the prospective Submitters, at any time choose to discontinue this RFP without obligation to such prospective Submitters.

DELIVERABLES

At the conclusion of the assessment, ISSC requires written documentation of the approach, findings (including statistical analysis of the results), and recommendations associated with this project (including an Executive Summary).

FINAL REPORT

A document developed to summarize the scope, approach, findings and recommendations, in a suitable format.