

# Interstate Shellfish Sanitation Conference



## Work Plan Evaluation for

January 1, 2017 – December 31, 2017

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## I. INTRODUCTION

The Interstate Shellfish Sanitation Conference (ISSC) exists to provide formal structure for State regulatory authorities and shellfish industry representatives to participate in establishing guidelines and procedures for uniform and consistent application of the National Shellfish Sanitation Program (NSSP). The ISSC accomplishes this by assisting with the adoption of sound uniform procedures into the NSSP Guidelines that protect the health of the public by ensuring that the harvest, storing, shipping, processing and preparation of shellfish that is made available for consumption is as safe as possible. The ISSC is also responsible for promoting mutual respect and trust among the state programs and participants and resolving disagreements between regulatory and industry partners involved with the ISSC and its activities.

The ISSC has its Executive Office in Columbia, SC. The Conference is responsible for three primary tasks; (1) the planning and execution of the Biennial Conference, the Executive Board Meetings and various other committee meetings; (2) communication of essential shellfish program information among the U.S. Food and Drug Administration (FDA), National Oceanic and Atmospheric Administration (NOAA), Environmental Protection Agency (EPA), state regulatory authorities, members of the shellfish industry, the ISSC and (3) facilitation of the Model Ordinance implementation. The Executive Office carries out these three programs through cooperative relationships with federal agencies (FDA, NOAA, and EPA), states and the shellfish industry. The Executive Office provides guidance policy, interprets the Model Ordinance, and evaluates all aspects of the National Shellfish Sanitation Program. The Conference currently has three (3) full time equivalent (FTE's) positions. This work plan has been developed with this staffing complement.

## II. EXECUTIVE SUMMARY

### A. Projected Tasks

The following tasks were successfully completed in 2017:

<u>Task Description</u>	<u>Was task completed?</u>
<b>PROJECTS</b>	
Biennial Meeting (1)	Y
Executive Board Meetings (2)	Y
Reduced Oxygen Packaging (ROP) Workshop (1)	Y
Biotoxin Workshop (1)	Y
Other Committee Meetings (25)	Y
Committee Conference Calls (As Needed)	Y
Grant Application for FDA Cooperative Agreement (1)	Y
Grant Application for Small Conference Grant (1)	Y
Update NSSP Guide (1)	Y
<b>COMMUNICATIONS</b>	
Annual Updates to Regional & National Conferences (5)	Y
Finalize Redesign of Website (1)	Y*
Update and Maintenance of Website (As Needed)	Y
Development and Distribution of Educational Materials (As Needed)	Y
Notification to States Concerning Shellfish Recalls/Closures (As Needed)	Y
ISSC/FDA Conference Calls (Monthly)	Y
ISSC/FDA/CDC Illness Reporting Conference Calls (Monthly)	Y

FACILITATION

Initiation of FDA Interpretations of the Model Ordinance (As Needed)	NONE REQUESTED
Assistance to States in resolving FDA Compliance Issues (As Needed)	Y
Assignments from Committees and Subcommittees (As Needed)	Y
Agency Interactions (As Needed)	Y

FINANCIAL ACCOUNTING

Grant Administration (3) (see III. A. 3.)	Y*
Budget Development (4)	Y
Budget Implementation (4)	Y

B. Program Issues/Concerns

Laboratory Methods:

Assist the Committee by acquiring and developing needed data to review newly proposed laboratory methods.

Male Specific Coliphage (MSC):

Develop Guidance Document to submit as a proposal for adoption at the 2017 Biennial Meeting.

Biotoxins:

Assess Biotoxin testing inconsistencies in current state practices. Develop a Guidance Document for Marine Biotoxin Contingency Plans that includes guidance for development of end-product testing programs to address Biotoxins in closed state waters.

Reduced Oxygen Packaging (ROP):

What is the need for requirements to address the risk of *C. botulinum* associated in reduced oxygen packages in the National Shellfish Sanitation Program (NSSP).

Vibrios:

Annually review trends in Vibrio illnesses. Collaborate with the Education Committee on Vibrio education issues and recommendations. Continue to monitor the activities and report annually to the VMC regarding the development of a process for using local data including regional or state illnesses and landings information, to more accurately reflect risk in a region or state. Continue to monitor the activities and report annually to the VMC regarding how best to estimate consumption patterns, including collection data regarding the number of shellfish consumed per serving, through market research, end-point consumer data, or other information gathering methods. Form a subcommittee to evaluate the effectiveness of existing NSSP regulations to reduce risk of Vibrio illnesses caused by improper handling, storing, or transportation of shellstock; to identify areas within the NSSP needing improvement; and make recommendations to the ISSC. The subcommittee will consist of FDA, state and industry representatives. Evaluate existing NSSP regulations to reduce risk of Vibrio illnesses caused by improper handling, storing, or transportation of shellstock and the effectiveness of existing enforcement mechanisms.

Aquaculture:

Revise the Model Ordinance Aquaculture chapter to reflect current practices.

### III. PRIORITIES

#### A. Executive Office

The highest priority for the Executive Office during this year was to ensure that the proposals and proceedings from the Biennial Conference were documented and properly prepared prior to forwarding the Summary of Actions to FDA for review. The second priority was the continued facilitation of the uniform implementation of the National Shellfish Sanitation Program according to the requirements in the Model Ordinance provided in the Guide to the Control of Molluscan Shellfish.

##### 1. Conference Follow up

The highest priority for the Executive Office in the year was to make sure the results and proceedings or Summary of Actions from the Biennial Conference were documented and disseminated to the appropriate agencies, groups and individuals. Once the FDA had reviewed the proposals and concurred or not concurred with the Summary of Actions, the Executive Office incorporates these proposal outcomes as a new revision to the NSSP Guide for the Control of Molluscan Shellfish. These actions are designed to provide a legislative mechanism by which states can effectively regulate shellfish in interstate commerce. While this type of cooperative approach is productive, it is quite time consuming and labor intensive. The Conference carries with it a great deal of responsibility to communicate with FDA and other ISSC partners to ensure that the recommendations that are proposed and approved by the Conference are documented properly and presented to FDA for review, approval and inclusion into the NSSP Guide for the Control of Molluscan Shellfish.

*There were no program deficiencies noted in 2017.*

##### 2. Communications

The Conference must continue to effectively communicate with FDA, NOAA, EPA, states and the Industry concerning the importance of protecting the public's health while ensuring the availability of shellfish that is safe to consume. It is necessary to advise, alert and notify these groups as issues develop that involve harvest area closures, consist of product recalls, emerging public health issues, or other information that may be of imminent concern to the membership and public at large.

The Conference has become the recognized leader in shellfish safety. Communicating information and educating the public about the impact of shellfish consumption and the potential hazards continues to be an increasingly difficult and complex effort. With naturally occurring toxins, viruses and bacteria as potential public health threats the Conference's mission has never been more important.

*There were no program deficiencies noted in 2017.*

##### 3. Financial Accounting

The main priority in the area of financial accounting was ensuring that the funds received by the Conference are managed as required. It is also imperative that the Conference be able to document and account for all funds received through the Executive Office (i.e., dues, registration fees, etc.). All grants were to be managed to ensure compliance with the award terms and conditions. The ISSC

budget was implemented consistent with Executive Board approval.

***The following program deficiencies were noted in 2017:***

*In April of 2018, the ISSC Executive office became aware that accounting information for several previous years had not been properly documented or incorporated into the ISSC financial accounting system. Steps were immediately taken to correct this situation. As of September 1<sup>st</sup>, 2018, all financial information was properly documented. Procedures have been implemented to ensure that this deficiency does not reoccur.*

IV. WORK PLAN EVALUATION

The 2018 Work Plan Evaluation will be submitted to the Executive Board for review prior to the Fall 2018 meeting.

V. WORK LOAD ACCOMPLISHMENTS

A. Planning

1. Biennial Meetings

The highest priority projects within the Executive Office involve the Biennial Meeting, the Executive Board meetings and all other committee and subcommittee meetings. Coordination of selection of site and meeting arrangements are critical to the success of the meetings.

2. Executive Board Meetings

The Executive Office prepares the materials for two Executive Board and committee meetings as needed and communicates with the groups should issues arise or information need to be disseminated between the Biennial Conference periods. This communication is vital in keeping Board Members informed of current and emerging issues as well as Conference business.

3. Other ISSC Committees

The Executive Office coordinates the activities of the committees listed below: Aquaculture, Biotoxin, Audit, Communications, Education, Foreign Relations, Growing Area Classification, Import Assessment, Labeling, Laboratory, Model Ordinance Effectiveness Review, NSSP Evaluation Criteria, Patrol, Plant Standardization Advisory, Production Reporting, Proposal Review, Reduced Oxygen Packaging, Research Guidance, Resolutions, Shellfish Restoration, Shellstock Resubmerging, Time Temperature, Traceability, Unresolved Issues, Use of Press, Vibrio Management, and Vv Illness Review.

B. Communications

1. Annual Updates at Regional Shellfish Conferences

The Executive Office prepares and the Executive Director provides updates of the ongoing activities of the Conference and the Executive Office at each of the regional shellfish conferences. This presentation is given to regional shellfish group meetings and other external constituencies that have interests in shellfish sanitation. Included in these groups are state officials, members of academia and the shellfish industry. These meetings provide a forum for the exchange of information to communicate changes in policies adopted by the Conference that

impact the shellfish industry.

2. Maintain and Enhance ISSC Website

Executive Office staff, with the assistance of an internet technology provider, manages and maintains the web site that provides information about the ISSC and its functions. The web site also provides documentation of previous Conference proceedings, ongoing and relevant information regarding shellfish sanitation, and linkages to sites that are relevant to issues regarding shellfish sanitation. Executive staff and staff from the internet technical provider continually update the web site to ensure that current information is accessible to regulatory and industry members as well as consumers.

3. Projects:

The Conference will assist in the development of guidance for use by states and the industry in conducting voluntary recalls. The guidance should address but is not limited to factors which should be considered in determining the extent of the risk from harvest area, the amount of Shellstock and the time period of harvest to include in the recall.

The Conference will provide guidance and administrative oversight to promote a coordinated effort among states, industry and the FDA to:

- a. 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;
- b. Ensure that the results of research efforts will be fully considered by the membership of the ISSC.

The Conference will collect data from states and industry for Vibrio Management data and information relative to efforts in their respective state associated with time and temperature assessment and control activities.

4. Notification of Shellfish Closure, Recall and Reopening

The Conference plays a critical role in communicating information and coordinating responses on shellfish closures, recalls, and reopenings to the appropriate state agencies. This timely communication ensures that recalls are performed as quickly as possible to minimize health risks from shellfish that may be associated with a shellfish borne disease outbreak.

C. Facilitation

1. Initiating FDA Interpretations of the Model Ordinance

The Executive Office receives numerous inquiries concerning interpretations of the Model Ordinance. In response to these inquiries, the Executive Office performs two functions. One is to assist individuals in understanding interpretations. The second is to request that interpretations be developed by the FDA.

2. Assist States in Resolving FDA Compliance Issues

Should the FDA and states disagree over the findings of a State Shellfish Sanitation Program evaluation and are unable to resolve these differences; the Executive Director is often requested to provide assistance. This role is critical in resolving issues. The work of the Executive Director can often assist affected

parties in avoiding the formal Unresolved Issue Process of the Conference. In the instances where there is disagreement in the evaluation of a State Shellfish Sanitation Control Program the Executive Director is looked upon as one of the first steps for resolution to a disagreement.

3. Assignments from Committees and Subcommittees

The Executive Office staff often receives tasks to complete and provides follow up for committee, subcommittee, task forces and work group meetings. Executive Office staff also tracks progress of these groups and provides technical and logistical assistance.

4. Agency Interactions

The Conference works cooperatively with other governmental agencies in the pursuit or advancement of issues concerning shellfish sanitation. These projects enhance the ability of the Conference to accomplish its mission and Executive Board objectives.

5. Training

It is necessary to continually assure that the Executive Office staff is adequately trained in Conference policies and procedures to maximize efficiency. Additionally, the staff is provided with training opportunities to advance their knowledge, skills and abilities to maximize their performance. Providing opportunities for advancing technical knowledge, skills and abilities of the Executive Office staff are of critical importance to the Conference.

D. Financial Accounting

1. Grant Administration

The Conference has successfully obtained grants that assist in the administrative costs of the day to day operations of the Executive Office. These grants address specific activities that deal with issues that are important to the conference.

***The following program deficiencies were noted in 2017:***

*In April of 2018, the ISSC Executive office became aware that accounting information for several previous years had not been properly documented or incorporated into the ISSC financial accounting system. Steps were immediately taken to correct this situation. As of September 1<sup>st</sup>, 2018, all financial information was properly documented. Procedures have been implemented to ensure that this deficiency does not reoccur.*

2. Budget Development

The Executive Office works to develop a general revenue operating budget that focuses on the costs of the Biennial Meeting and a portion of the Executive Office operating budget. Grant specific budgets are developed, monitored and implemented for adherence to the fiscal requirements established and required by the granting agencies.

3. Budget Implementation

The Executive Office implements the budgets as adopted by the Conference Executive Board. This involves assuring that monies are spent appropriately within each budget category and that amounts designated with these categories are not exceeded. The tracking of expenditures and prompt payment of accounts payable is a primary focus of the financial accounting function.

4. Audit

The Executive Office works with the Audit Committee to assure that the budgets developed and implemented are properly audited. The Executive Office provides guidance to the Audit Committee concerning current financial operations and audit controls practiced by the Executive Office. Additionally, the Executive Office implements any supplementary directives from the Audit Committee or auditor.

***The following program deficiencies were noted in 2017:***

*In April of 2018, the ISSC Executive office became aware that audits had not been completed as outlined in the ISSC Constitution Bylaws and Procedures. Steps were immediately taken to correct this situation. As of September 1<sup>st</sup>, 2018, the accounting firm of Moore Beauston and Woodrow LLP has reviewed recent financial information and will provide a report findings to the Executive Board at the 2018 Fall Board Meeting.*

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